

Department of Microbiology
QC Procedures
Entering New Lots in LIS

Start:

FUNCTION: MQCE <enter>

Next Screen:

Tech Code: **YOUR # and NAME** will display <enter>

Shift: <enter> for current shift

Lab I.D.: type in **SHM**

Bench/Rack: type in **TESTQC**

Next Screen:

Select 1 →

Main Menu	
1.	Lot Entry
2.	Scheduled Quality
3.	Pending Result Entry
4.	Manufacturer Entry
5.	Grid Result Entry

Next Screen:

	Enter manufacturer code		Enter lot #
MFG Code	:	<input type="text"/>	Lot Number :

Item(s) : enter item code* or hit Home key to look up (hit End key to select)

Procedure(s) : <enter>

Received Date : enter date received

Active Date : enter current date

Inactive Date : hit <enter>

Expiration Date : enter date product expires

Quantity : <enter>

Note : <enter>

* After entering an item, a pop-up box will appear so you can inactivate old lots. Use this option if old lots are expired or no longer in use. Select lots to inactivate by hitting the End key to select, then hit <enter>.

Modify **Accept** Reject

Department of Microbiology
QC Procedures
Entering QC Results in LIS

Start:

FUNCTION: MQCE <enter>

Next Screen:

Tech Code: **YOUR # and NAME** will display <enter>

Shift: <enter> for current shift

Lab I.D.: type in **SHM**

Bench/Rack: type in **TESTQC**

Next Screen:

Select 2 →

Main Menu	
1.	Lot Entry
2.	Scheduled Quality Control
3.	Pending Result Entry
4.	Manufacturer Entry
5.	Grid Result Entry

Next Screen:

Schedule Date: <enter> for current date

Schedule Shift: <enter> for current shift

Select appropriate category. Items not on weekly QC can be found under UNSCHEDULED →

Category	Type	Status
MEDIA	sch	
STAINS	sch	
RGNT	sch	
UNSCHEDULED		

Next Screen:

Item: enter code or look up by hitting Home key

Example:

Next Screen:

Item: **INDOLE**

Select lot # →

Lot Number	MFG	Received	Expiration
223775-1	PML	12/29/2006	03/12/2007
223469-1	PML	12/13/2006	03/05/2007

Next Screen:

Item	Lot Number	Procedure rc	Result
INDOLE	223775-1	E25922	
	223775-1	KP882	

↑
Enter results.
Consult the QC Reference Guide
for the appropriate response entry
(POS, NEG, or OK).

Entering Failed QC Test Results

- If the QC testing failed, enter the appropriate result (POS, NEG, or ;INVAL).
- A message will appear that reads, **A QUALITY CONTROL FAILURE HAS OCCURRED.** Hit <enter>
- You will be asked for a **Failure Code.** Hit the Home key to pull up a list of failure codes.
- Arrow down through the list to select the appropriate entry, such as **WREP (Will Repeat)** and then hit <enter>. The result will now appear in red.

Item	Lot Number	Procedure rc	Result
INDOLE	086712	E25922	NEG
	086712	KP882	

- If the results from repeated testing are completed on the same shift, you can enter a corrective action comment under the failed result. To do this, use the arrow keys to place the cursor over the failed result.
- Hit the “4” key on the 10-key keypad.
- Select, “Corrective Action Comment” and hit <enter>.
- Select, “Edit” and hit <enter>.
- Free text in a description of corrective actions and any resolution.
- When finished, hit the Num Lock key.
- After the “Command” prompt, hit “E” to exit and the hit <enter>.
- After “Save and exit are you sure?” hit “Y” for yes.
- The result will now appear with a small plus sign indicating that there is a comment associated with the result.
- Hit the F11 key and accept the entry.

Item	Lot Number	Procedure	rc	Result
INDOLE	086712	E25922	+	NEG
	086712	KP882		

Department of Microbiology
QC Procedures
Looking Up QC Results in LIS

Start:

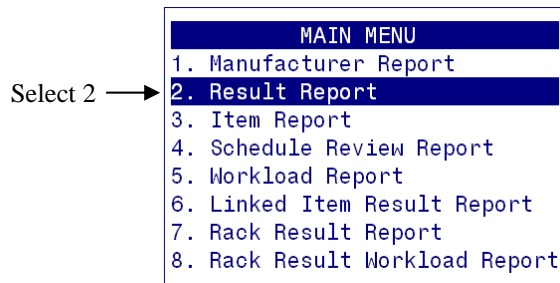
FUNCTION: MQCR <enter>

Next Screen:

QUALITY CONTROL ENTRY REPORTS

PRINTER: 0

Next Screen:



Next Screen:

Lab I.D.: SHM

Next Screen:

SACRED HEART MICRO Q		Quality Control Result Report	03/10/2010
Bench Code(s)	:	All	
Start Date	:	02/08/2010	
End Date	:	03/10/2010	
Category Code(s)	:	All	
Item Code(s)	:	All	
Sort Sequence	:	BNCH,CAT,ITEM,DATE	
Failure Only (Y/<N>)	:	N	
Comments (Y/<N>)	:	N	
Detail/Summary (D/<S>)	:	S	

1. Hit enter to Modify.
2. Enter appropriate start date. Check to see when the item in question was received. This date should be written on the item or box.
3. Enter the item code or look up the item by hitting the “Home” key and then the “End” key to select the item.
4. Enter down to the Accept option.
5. Review QC data to see if the lot number and receive date for the item in question can be found. If no record of QC is found, perform QC and enter results in LIS.

Department of Microbiology
QC Procedures

10B Arginine Broth Medium

Frequency of QC testing

Each new lot or shipment

Control organisms

Ureaplasma urealyticum clinical isolate (-70°C freezer)

Mycoplasma hominis clinical isolate (-70°C freezer)

S. aureus ATCC 25923 (-70°C freezer)

Procedure

1. Remove a 10B Arginine vial and allow to reach room temperature. Obtain stocks of control organisms from freezer and allow vials to thaw.
2. Using a sterile transfer pipette, transfer thawed QC organism suspensions to 3 separate 10B Arginine vials. Incubate vials with patient test vials at $35 \pm 2^\circ\text{C}$ until pink color change is visible.
3. Document results in LIS.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: B10

Results: Mycoplasma (POS), Ureaplasma (POS), *S. aureus* 25923 (NEG)

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures
A7/A8 Agar Medium

Frequency of QC testing

Each new lot or shipment

Control organism

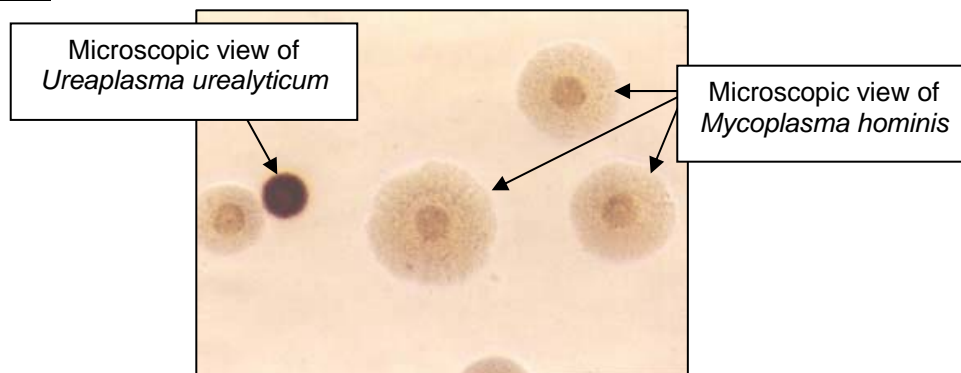
Mycoplasma hominis clinical isolate (-70 °C freezer)

Ureaplasma urealyticum clinical isolate (-70 °C freezer)

Procedure

1. Remove A7 or A8 agar from the refrigerator and allow to reach room temperature. Obtain frozen stock of control organisms from freezer and allow vial to thaw at room temperature.
2. Both organisms may be inoculated onto the same plate. Dip a sterile swab into the stock culture and streak a lawn of inoculum onto the agar.
3. Tape the plate and incubate with patient cultures in CO₂ atmosphere inside moist chamber at 35 ± 2 °C for 3-5 d.
4. Examine agar surface microscopically (10X) to detect typical, large, colorless, “fried egg” colonies that are characteristic of *M. hominis*. *U. urealyticum* colonies will appear smaller, golden brown, round, and coarsely granular with rough edges.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: A7 or A8

Results: OK

Entering New Lots

MFG Code: BBL, HARDY, or REMEL

Department of Microbiology
QC Procedures
Anaerobe ID Disks

Frequency of QC testing

Each new lot or shipment, assigned

Control organisms

Fusobacterium nucleatum ATCC 25586 (kept in -70 °C freezer)

Bacteroides fragilis ATCC 25285 (kept in -70 °C freezer)

Peptostreptococcus ATCC 29743 (kept in -70 °C freezer)

Procedure

1. Label 3 brucella blood agar plates with date and names of respective control organisms.
2. Prepare a cell suspension of each control organism in TSB to a turbidity approximately equal to a 0.5 McFarland standard.
3. Using a sterile swab, inoculate a lawn of each control organism onto the surface of the 3 separate brucella blood agar plates.
4. Apply disks at least 20 mm apart on the surface of the plates (see Expected Results below for set-up).
5. Incubate the plates anaerobically at 35-37 °C for 24 to 48 h and then examine for zones of inhibition.

Expected Results (zones of inhibition)

Control Organism	Bile Disk	Colistin 10 µg	Kanamycin 1 mg	Vancomycin 5 µg
<i>F. nucleatum</i> (25586)	≥ 10 mm (S)	≥ 10 mm (S)	≥ 10 mm (S)	≤ 10 mm (R)
<i>B. fragilis</i> (25285)	Growth up to disk (R)	≤ 10 mm (R)	≤ 10 mm (R)	≤ 10 mm (R)
<i>Peptostrep.</i> (29743)	ND	ND	ND	≥ 10 mm (S)

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: ANABI, ANACL, ANAK, ANAVA

Results: S (K key) or R (L key)

Entering New Lots

MFG Code: BD

Department of Microbiology
QC Procedures
API 20E Kit

Frequency of QC Testing

Each new lot or shipment, assigned

Control Organisms

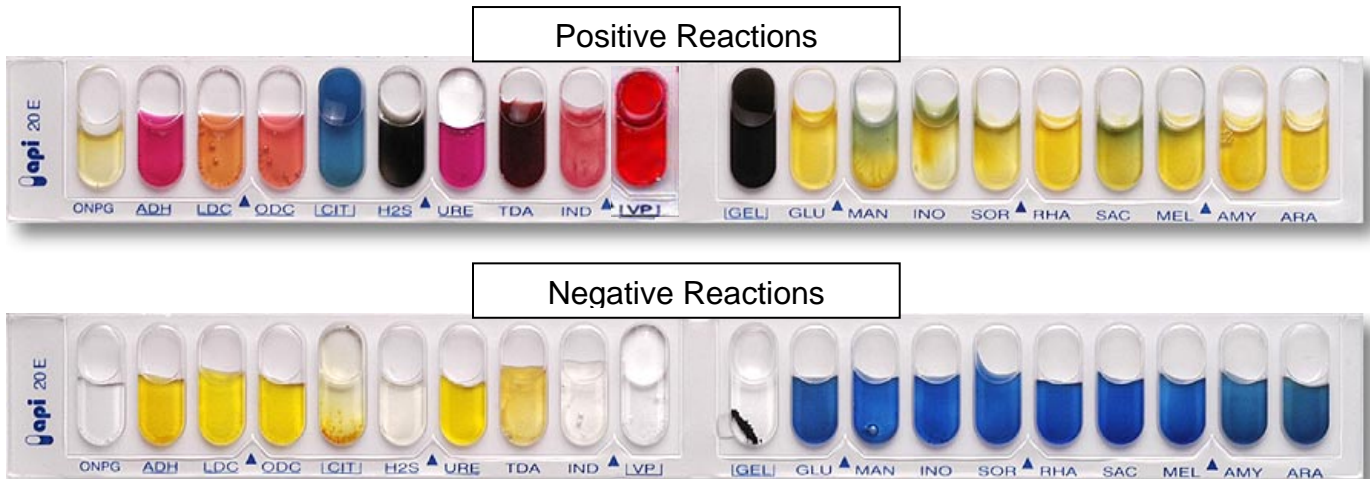
1. *E. coli* ATCC 25922 (sub from monthly stock slant in refrigerator)
2. *Stenotrophomonas maltophilia* ATCC 51331 (sub from stock kept in -70 °C freezer)
3. *Enterobacter cloacae* ATCC 13047 (sub from stock kept in -70 °C freezer)
4. *Proteus mirabilis* ATCC 35659 (sub from monthly stock slant in refrigerator)
5. *Klebsiella pneumoniae* ATCC 35657 (sub from stock kept in -70 °C freezer)

Procedure

Prepare and inoculate test strips following API 20E procedure.

Expected Results

	ONPG	ADH	LDC	ODC	CIT	H ₂ S	URE	TDA	IND	VP	GEL	GLU	MAN	INO	SOR	RHA	SAC	MEL	AMY	ARA	NO ₂	N ₂
1	+	-	+	+	-	-	-	-	+	-	-	+	+	-	+	+	-	+	-	+	+	-
2	+	-	V	-	V	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
3	+	+	-	+	+	-	-	-	-	+	-	+	+	-	+	+	+	+	+	+	+	-
4	-	-	-	+	V	+	+	+	-	-	V	+	-	-	-	-	V	-	-	-	-	+
5	+	-	+	-	+	-	V	-	-	V	-	+	+	+	+	+	+	+	+	+	+	-



Computer Entry of Results

Function: MQCE
Select: TESTQC
Category: UNSCHEDULED
Item Code: APIE
Results: OK

Entering New Lots

MFG Code: BIOMER

Department of Microbiology
QC Procedures
API CORYNE Kit

Frequency of QC Testing

Each new lot or shipment, assigned

Control Organisms

1. *Corynebacterium renale* ATCC 19412 (kept in -70 °C freezer)
2. *Cellulosimicrobium cellulans* ATCC 27402 (kept in -70 °C freezer)
3. *Microbacterium testaceum* ATCC 15829 (kept in -70 °C freezer)
4. *Listeria grayi* ATCC 25401 (kept in -70 °C freezer)

Procedure

Prepare and inoculate test strips following API CORYNE procedure.

Expected Results

	NIT	PYZ	PyrA	PAL	BGUR	BGAL	αGLU	βNAG	ESC	URE	GEL	O	GLU	RIB	XYL	MAN	MAL	LAC	SAC	GLYG	CAT	
1	-	+	-	-	+	-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-	+
2	+	+	+	+	-	+	+	+	+	-	V	-	+	+	+	-	+	-	+	V	+	
3	-	+	-	V	-	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	+
4	V	V	-	-	-	-	V	+	+	-	-	-	+	+	-	+	+	+	+	-	-	+

Positive Reactions



Negative Reactions



Computer Entry of Results

Function: MQCE
Select: TESTQC
Category: UNSCHEDULED
Item Code: APIC
Results: OK

Entering New Lots

MFG Code: BIOMER

Department of Microbiology
QC Procedures

Auramine-Rhodamine Stain for AFB

Frequency of QC testing

Each time of use

Control organisms

Positive control slide (previous positive patient specimen)

Negative control slide (*E. coli*)

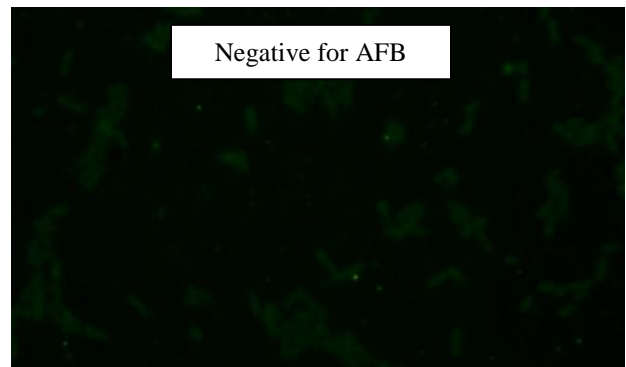
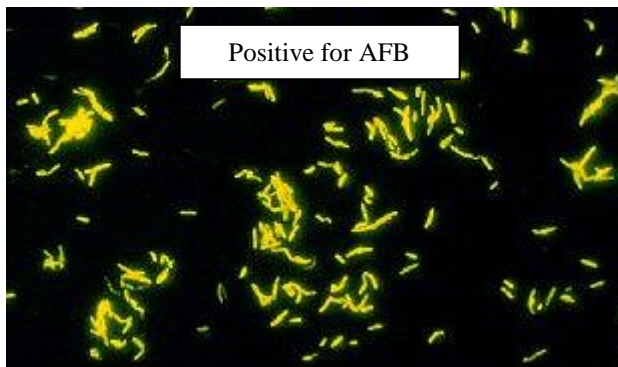
Procedure

1. Flood smears with auramine-rhodamine stain for 15 min.
2. Rinse slides with tap water.
3. Decolorize thoroughly using 0.5% HCL in 70% ethanol. Allow at least 2 min to decolorize.
4. Rinse with tap water.
5. Counterstain with potassium permanganate for 2 min.
6. Rinse with tap water and allow to air dry.
7. Examine control smears on 20X and 40X prior to reading patient smears.

Expected Results

Positive control: yellow-orange fluorescing bacilli

Negative control: no fluorescing organisms



Computer Entry of Results

Function: MQCE

Select: **TBQC**

Category: Daily under STAINS

Item Codes: AFBSTN

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

BCSA (*B. cepacia* Selective) Agar Medium

Frequency of QC testing

Each new lot or shipment

Control organism

Burkholderia cepacia ATCC17765

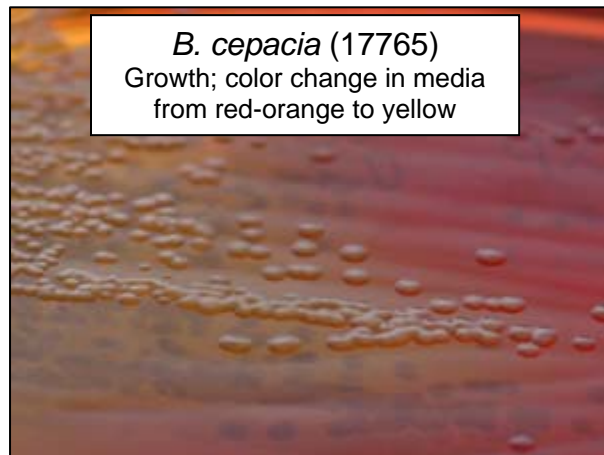
Pseudomonas ATCC 27853

Staphylococcus aureus ATCC 25923

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar sub plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:10 in normal saline.
3. The *S. aureus* (25923) inoculum and *P. aeruginosa* (27853) inoculum may be combined and inoculated onto one agar plate.
4. Using a 10- μ L loop (large urine loop), inoculate the agar and streak for isolation.
5. Incubate media in an ambient atmosphere at 35 °C for 24-72 h.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BCSA

Results: POS, NEG, and NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures
BCYE Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organism

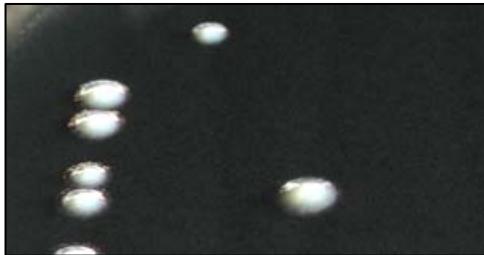
Legionella pneumophila ATCC 33152

Procedure

1. Working in the biological safety cabinet, make basic cell suspensions for each test strain directly from growth on weekly sub plates and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspensions 1:100 in normal saline.
3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Mark the *Legionella* culture log with QC final in 3 days.
5. Incubate media in ambient atmosphere at 35 °C for 72 h. Colonies of *Legionella* should appear white-gray.

Expected Results

Colonies of *Legionella* should appear as white to gray colonies.



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BCYE

Results: POS

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures

BCYE Selective Agar Medium w/PAC

Frequency of QC testing

Each new lot or shipment when received

Control organism

Legionella pneumophila ATCC 33152 (weekly sub)

Procedure

1. Working in the biological safety cabinet, make a basic cell suspension directly from growth on weekly sub plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:10 in normal saline.
3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Mark the *Legionella* log with QC final in 3 days.
5. Incubate media in ambient atmosphere at 35 °C for 72 h. Colonies should appear white-gray.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BCYES

Results: POS

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
BD Affirm Kit

Frequency of QC Testing

Kits: Each new lot/shipment and weekly using external control material

Internal Controls: Each card contains an internal positive and negative control

Heat Block temp: Each shift test is performed

Control Organisms for Kit QC

Trivalent Control, which contains suspensions of *Candida albicans* ATCC 90028, *Gardnerella vaginalis* ATCC 1048, and a clinical culture isolate of *Trichomonas vaginalis*.

Negative control: suspension of *E. coli* ATCC 25922

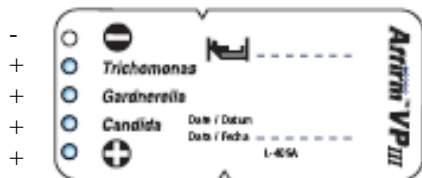
Procedure

1. Remove controls from -70C freezer and allow thawing at room temperature.
2. Using the scored swabs and tubes from the BD Affirm kit, prepare controls by soaking separate swabs in each suspension. Label each tube accordingly.
3. Process samples in the same manner as clinical samples.
4. Alternate QC testing between each instrument and document on log.

Expected Results

After processing, the reaction cards should be interpreted using a white background. Any blue color on the beads indicates a positive result. No color indicates a negative. Check to ensure that the internal controls have reacted appropriately. The Trivalent Control should yield positive results for each of the 3 analytes. The negative control material should yield negative results for each of the 3 analytes.

Illustration of Trivalent QC



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: Heat block temp is under SCHEDULED and kit QC is under UNSCHEDULED

Item Codes: BDVPHB (temp), VPCRD (kit)

Results: enter as POS or NEG

Entering New Lots

MFG Code: BD

Item: VPCRD

Department of Microbiology
QC Procedures
BHI Broth

Frequency of QC testing

Each new lot/shipment

Control organisms

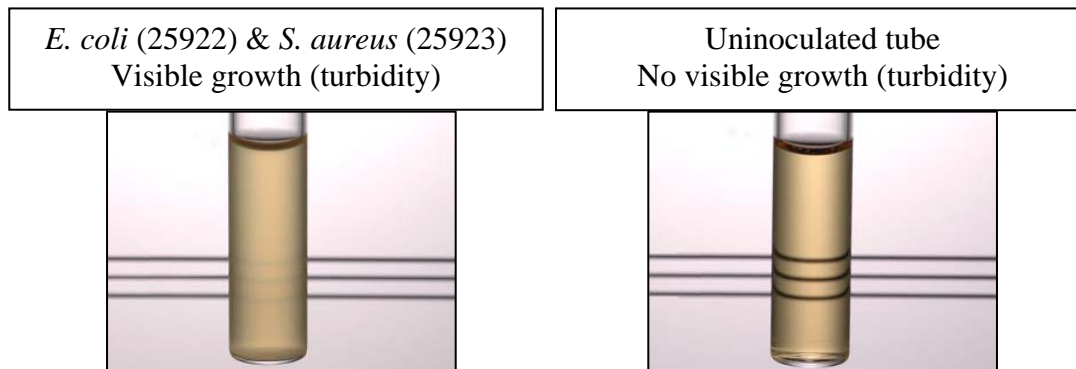
S. aureus ATCC 25923

E. coli ATCC 25922

Procedure

1. Label 3 tubes of BHI broth with date and each of the control organism names, plus one tube as uninoculated.
2. Using a sterile inoculating loop, select and remove an isolated colony of control organism and lightly inoculate appropriate tube. The third tube should remain uninoculated.
3. Incubate both tubes in an ambient atmosphere at 35°C for 24 h.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BHIBR

Results: POS or NEG

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures

BHI Broth with 6.5% NaCl

Frequency of QC testing

Each new lot/shipment

Control organisms

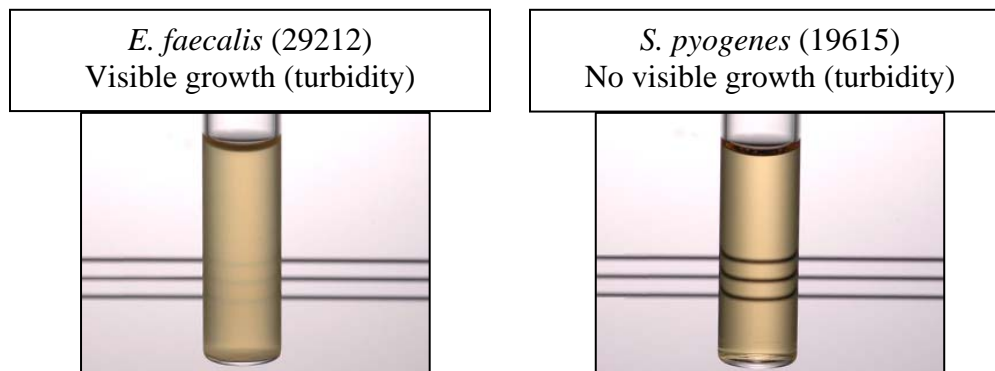
Enterococcus faecalis ATCC 29212

Streptococcus pyogenes ATCC 19615

Procedure

1. Label 2 tubes of BHI 6.5% NaCl broth with date and each of the control organism names.
2. Using a sterile inoculating loop, select and remove an isolated colony of control organism and lightly inoculate appropriate test tube containing salt broth.
3. Incubate both tubes in an ambient atmosphere at 35 °C for 24 h.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: NACL65

Results: POS or NEG

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
Bird Seed Agar

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Cryptococcus neoformans ATCC 14116

Candida albicans ATCC 90028

Staphylococcus aureus ATCC 25923

Procedure

1. Prepare a 0.5 McFarland suspension of each test strain.
2. Dilute the suspension 1:10 with sterile saline.
3. Use a 0.01 mL calibrated loop to inoculate the medium.
4. Incubate plates at 25 - 30°C in an aerobic atmosphere for up to 5 days.

Expected Results

***C. neoformans* 14116**

Colonies pigmented tan to brown
within 5 days of incubation.



***C. albicans* 90028**

Growth w/no brown pigment.

***S. aureus* (25923)**

Partially inhibited growth.

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BSA

Results: POS, NEG, NEG

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
Caffeic Acid Disks

Frequency of QC testing

Each new lot or shipment, when received

Control organisms

Cryptococcus neoformans ATCC 14116

Cryptococcus albidus ATCC 10666

Candida albicans ATCC 90028

Procedure

1. Dispense 3 disks onto a glass slide.
2. Moisten each disk with 1 drop of water.
3. Place slide into a petri dish containing a moistened piece of filter paper to prevent the disks from drying out during incubation.
4. Using 48-72 h old cultures grown on a non-dextrose containing medium, inoculate each disk with five to six yeast colonies to yield a visible paste on the surface of the disks.
5. Replace the plate lid and incubate the disks aerobically at 35°C in the dark.
Observe for the development of dark brown pigmentation at 30 min intervals for up to 4 h.

Expected Results

C. neoformans 14116
Positive (brown)



C. albidus 10666 Neg
(no change or light tan)



C. albicans 90028
Negative (no change)



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CADQC

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures
Calcofluor White Stain

Frequency of QC testing

Perform QC with each batch of patient smears.

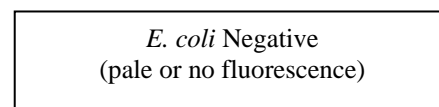
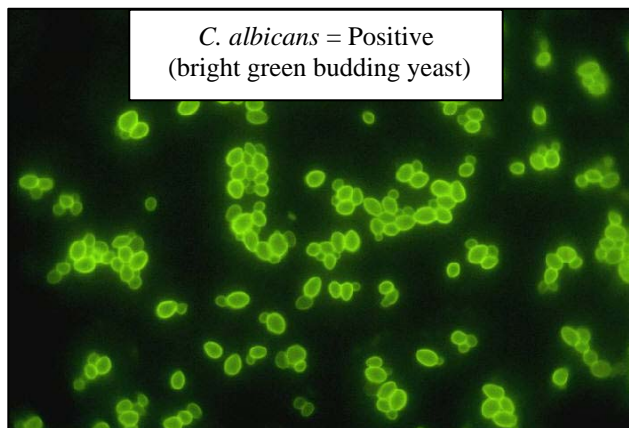
Control organisms

Candida albicans & *E. coli*

Procedure

1. The smears can be prepared with organism suspensions equivalent to a 0.5 McFarland.
Place a drop of each control suspension on separate slides and dry using a slide warmer.
2. Store slides in labeled boxes at room temperature.
3. Stain control slides using the same protocol as for patient smears.
4. Examine slides at x 100 and x 400 magnification using a fluorescent microscope.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CFWST

Results: POS or NEG

Entering New Lots

MFG Code: POLYSC

Department of Microbiology
QC Procedures
Campy CVA Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

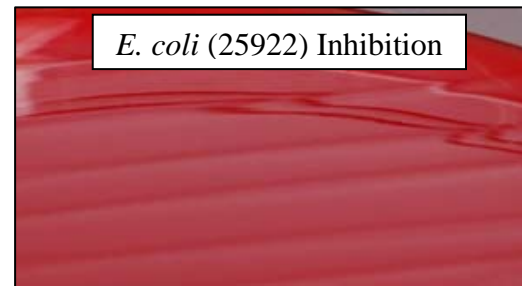
Campylobacter jejuni ATCC 33291

E. coli ATCC 25922

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the *E. coli* suspension 1:10 and the *C. jejuni* suspension 1:100 in normal saline.
3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Incubate media in microaerophilic atmosphere (Campy jar) at 42°C for 48 h.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CAMPY

Results: POS or NEG

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
CarboFERM Kit

Frequency of QC Testing

Each new lot or shipment, assigned


Control Organisms

1. *Neisseria lactamica* ATCC 23970 (weekly sub)
2. *Neisseria sicca* ATCC 9913 (sub from stock kept in -70 °C freezer)
3. *Moraxella catarrhalis* ATCC 25238 (weekly sub)

Procedure

Prepare and inoculate test strips following CarboFerm procedure.

Expected Results

	1	2	3	Test Organism	ATCC	Control	Glucose	Maltose	Lactose	Sucrose	Butyrate
	<i>N. lactamica</i>	23970	-	+	+	+	-	-			
	<i>N. sicca</i>	9913	-	+	+	-	+	-			
	<i>M. catarrhalis</i>	25238	-	-	-	-	-	+			

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CFERM

Results: OK

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures
Carrot Broth

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Strep agalactiae ATCC 12386

E. coli ATCC 25922

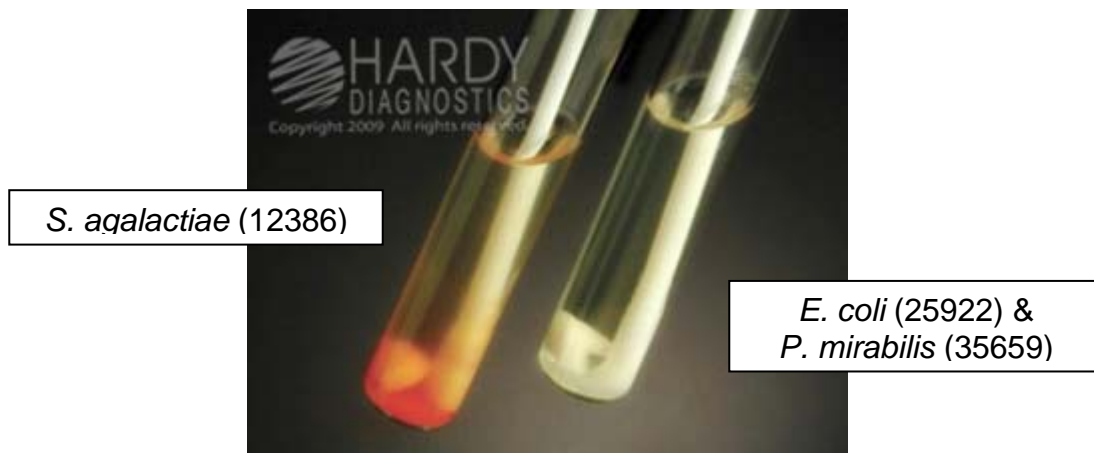
P. mirabilis ATCC 35659

Procedure

1. Prepare a 0.5 McFarland suspension of each test strain.
2. Dilute *S. agalactiae* ATCC 12386 1:100.
3. Dilute *E. coli* ATCC 25922 and *P. mirabilis* ATCC 35659 1:10. Combine suspensions into one mixture.
4. Use a 0.01 mL calibrated loop to inoculate two separate broths.
5. Incubate tubes overnight at 35 ± 2°C in an aerobic atmosphere.

Expected Results

Control strain	Expected Results
<i>S. agalactiae</i> ATCC 12386	Growth; bright orange color change
<i>E. coli</i> ATCC 25922 and <i>P. mirabilis</i> ATCC 35659	Partial to complete inhibition; no color change



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CRTBR (use when testing kits - broth with tiles included) or CRTBRT (use when testing separate, supplemental tiles)

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Kits - use the lot number on the box rather than the lot on the tubes or tiles.

Tiles only - use lot number on the tile container

Department of Microbiology
QC Procedures
Catalase Reagent

Frequency of QC testing

Each new lot

Control organisms

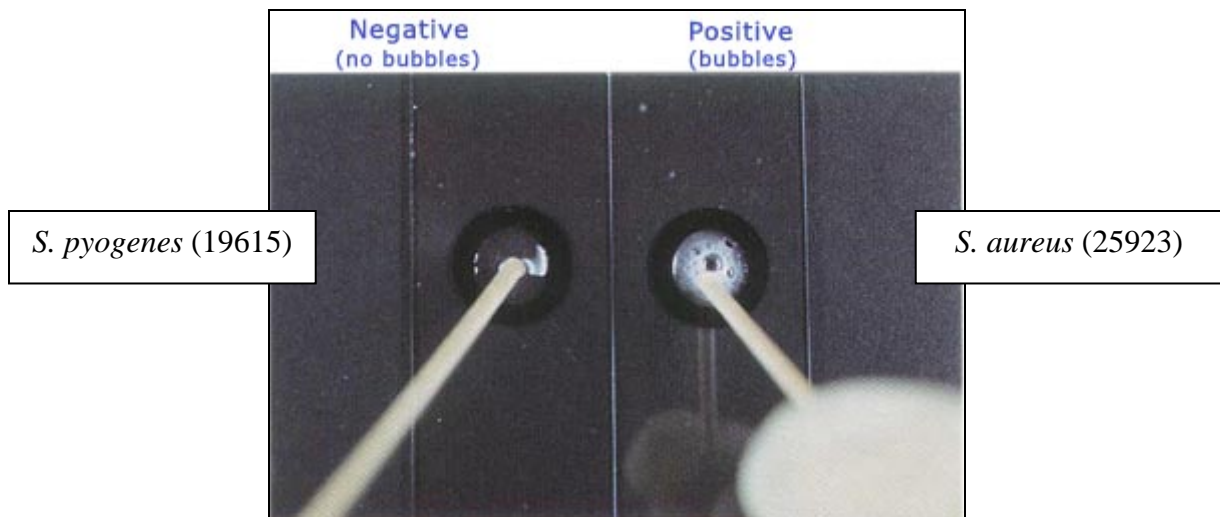
Staphylococcus aureus ATCC 25923

Streptococcus pyogenes ATCC 19615

Procedure

1. Place 1 drop of reagent on a glass slide.
2. With a wooden applicator, pick the center of an 18-24-h pure colony.
3. Inoculate control organism into reagent drop and observe reaction over a dark background.
4. Repeat for other control organism.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: CAT

Results: POS or NEG

Entering New Lots

MFG Code: SHM

Department of Microbiology
QC Procedures
Cdiff PCR BD MAX Kit

Frequency of QC Testing

Each new lot or shipment and every 30 d while in use.

Control Organisms

Clostridium difficile ATCC 43255 (toxigenic)

Clostridium difficile ATCC 700057 (non-toxigenic)

Procedure and Expected Results

External Controls

1. Suspensions of the control strains should be prepared in saline to a turbidity of 0.5 McFarland ($\sim 1.0 \times 10^8$ CFU/mL) from isolated colonies and subsequently diluted with saline to obtain a final concentration of $\sim 3.3 \times 10^5$ CFU/mL.
2. Suspensions may be frozen in aliquots at -70°C and thawed prior to use.
3. Dip a separate 10 μL loop into each bacterial suspension and inoculate the sample buffer tubes. Follow testing protocol outlined in the BD MAX™ Cdiff Assay Procedure.
4. All quality control results should be entered into the LIS. Notify supervisor if results are not as expected.

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MAXCD

Results for kit QC: NEG, POS

Entering New Lots

MFG Code: BD

Item: MAXCD

Department of Microbiology
QC Procedures

Cefinase (β -Lactamase) Disks

Frequency of QC testing

Each new lot or shipment, when opened

Control organisms

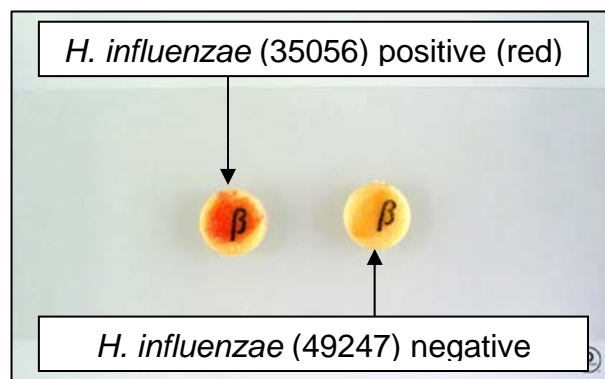
Haemophilus influenzae ATCC 35056

Haemophilus influenzae ATCC 49247

Procedure

1. Dispense 2 disks from the cartridge onto a glass slide.
2. Moisten each disk with 1 drop of water.
3. Smear several well-isolated colonies of control organism onto each disk using a wooden applicator.
4. Observe the disks for color change within 5 min.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BLACT

Results: POS or NEG

Entering New Lots

MFG Code: BD

Department of Microbiology
QC Procedures
CGB Agar

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Cryptococcus gattii ATCC MYA-4561

Cryptococcus neoformans ATCC 14116

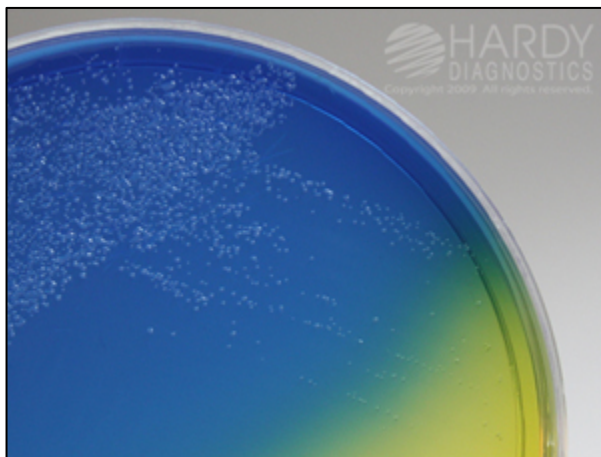
Procedure

1. Prepare a 0.5 McFarland suspension of each test strain.
2. Dilute the suspension 1:10 with sterile saline.
3. Use a 0.01 mL calibrated loop to inoculate the medium.
4. Incubate plates at 25 - 30°C in an aerobic atmosphere for up to 5 days.

Expected Results

***C. gattii* ATCC MYA-4561**
growth and a color change from
yellow-green to blue

***C. neoformans* 14116**
No growth or slight growth
with no color change



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CGB

Results: POS, NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures
Chocolate Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Neisseria gonorrhoeae ATCC 43069

Haemophilus influenzae ATCC 49247

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar sub plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:100 in normal saline.
3. Using a 10 μ L loop (large urine loop), inoculate the agar and streak for isolation.
4. Incubate media in CO₂ at 35 °C for 24 h.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CHOC

Results: POS

Entering New Lots

MFG Code: BBL

CHROMagar Candida Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Candida albicans ATCC 90028

Candida krusei ATCC 14243

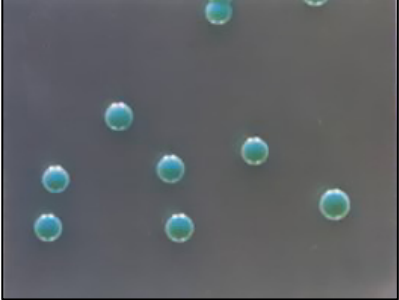


Candida tropicalis ATCC 750

Pseudomonas aeruginosa ATCC 27853

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:10 in normal saline.
3. Divide a CHROMagar Candida plate into quadrants for each of the 4 test strains.
4. Using a 10- μ L loop (large urine loop), inoculate the agar and streak for isolation.
5. Incubate media in the dark in ambient atmosphere at $35 \pm 2^\circ\text{C}$ for 36 - 48 h.

Expected Results

<p style="text-align: center;"><i>C. albicans</i> 90028</p>  <p style="text-align: center;">Light to medium green</p>	<p style="text-align: center;"><i>C. krusei</i> 14243</p>  <p style="text-align: center;">Large, spreading colonies with pink centers and rough, pale edges</p>
<p style="text-align: center;"><i>C. tropicalis</i> 750</p>  <p style="text-align: center;">Dark blue to blue-gray with a dark halo in the agar</p>	<p style="text-align: center;"><i>P. aeruginosa</i> 27853 Inhibition (partial to complete)</p>

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CHRMCA

Results: OK

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
CHROMagar MRSA II Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

S. aureus ATCC 43300

S. aureus ATCC 29213

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspensions 1:10.
3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Incubate media in ambient atmosphere at 35 ± 2°C for 24 h.

Expected Results

S. aureus (43300) mauve colonies

S. aureus (23213)
No growth or no mauve colonies



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CHRMR

Results: POS, NEG

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures

CHROMagar O157 Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

E. coli ATCC 700728

E. coli ATCC 25922

Enterobacter cloacae ATCC 13047

Procedure

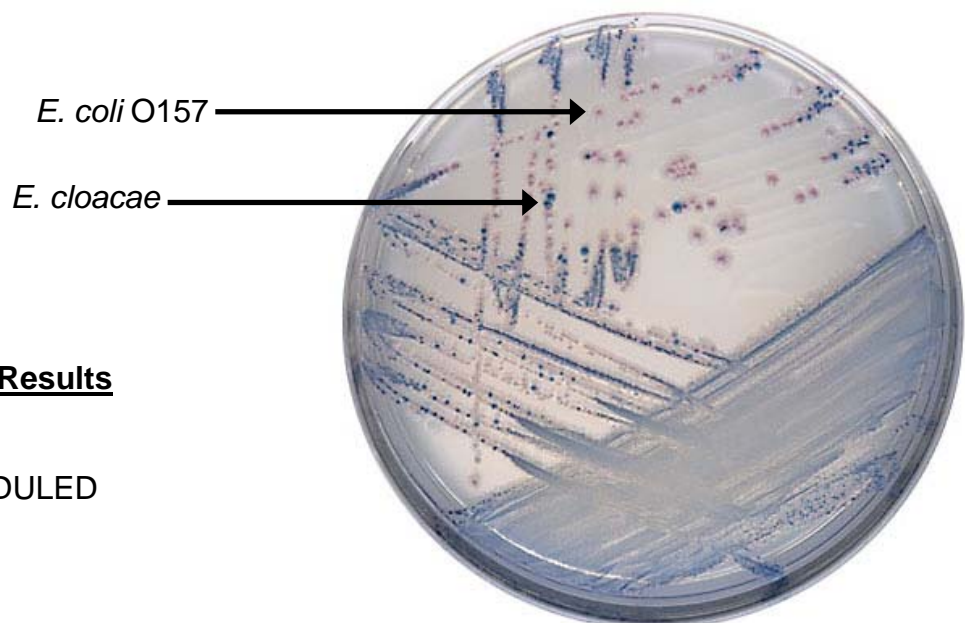
1. Make a basic cell suspension directly from growth of a fresh agar plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspensions as indicated below:

Control strain	Dilution
<i>E. coli</i> ATCC 700728	1 : 100
<i>E. coli</i> ATCC 25922	1 : 10
<i>E. cloacae</i> ATCC 13047	1 : 10

3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Incubate media in ambient atmosphere at 35 ± 2°C for 24 h.

Expected Results

Control Organism	Expected Results
<i>E. coli</i> ATCC 700728	Growth of mauve colonies
<i>E. coli</i> ATCC 25922	Inhibition (partial to complete)
<i>Enterobacter cloacae</i> ATCC 13047	Growth of blue-green to blue colonies



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CHRM01

Results: OK

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures

CHROMagar Orientation Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

E. coli ATCC 25922

Enterobacter cloacae ATCC 13047

Proteus mirabilis ATCC 35659

Enterococcus faecalis ATCC 29212


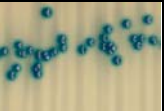


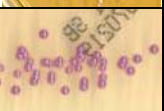

Staphylococcus saprophyticus ATCC 15305

Staphylococcus aureus ATCC 25923

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:100 in normal saline.
3. Inoculums can be combined so that two organisms can be inoculated onto one plate in order to save resources (e.g., *E. coli* + *E. cloacae*, *Enterococcus* + *S. aureus*, etc.)
4. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
5. Incubate media in ambient atmosphere at 35 ± 2°C for 24 h.

Expected Results

Control Organism	Expected Results	
<i>Enterobacter cloacae</i> ATCC 13047	Growth; medium size, dark blue to medium-blue colonies with or without violet halos in the surrounding medium	
<i>Enterococcus faecalis</i> ATCC 29212	Growth; small size, blue-green colonies	
<i>Escherichia coli</i> ATCC 25922	Growth; medium to large size, transparent, dark rose to pink colonies with or without halos	
<i>Proteus mirabilis</i> ATCC 35659	Growth; medium size, transparent, pale beige to brown colonies, surrounded by a brown halo. Swarming is partially to completely inhibited.	
<i>Staph saprophyticus</i> ATCC 15305	Light pink to rose, small opaque colonies with or without halos.	
<i>Staph aureus</i> ATCC 25923	Growth; small to medium size, white to cream (natural pigmentation).	

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CHRMAG

Results: OK

Entering New Lots

MFG Code: BBL

CHROMagar Salmonella Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Salmonella enterica ATCC 14028

E. coli ATCC 25922

Staph aureus ATCC 25923

Citrobacter freundii ATCC 8090

Procedure

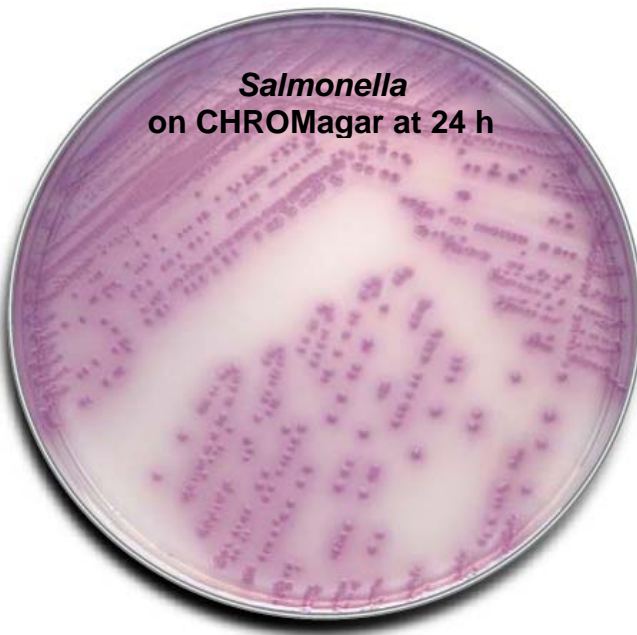
1. Make a cell suspension directly from growth of a fresh agar plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspensions as indicated below:

Control strain	Dilution
<i>S. enterica</i> ATCC 14028	1 : 100
<i>E. coli</i> ATCC 25922	1 : 10
<i>S. aureus</i> ATCC 25923	1 : 10
<i>C. freundii</i> ATCC 8090	1 : 10

3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation. The *E. coli* and *S. aureus* suspensions may be combined to inoculate the same plate.
4. Incubate media in ambient atmosphere at 35 ± 2°C for 24 h.

Expected Results

Control organism	Expected Results
<i>S. enterica</i> ATCC 14028	Growth of mauve colonies
<i>E. coli</i> ATCC 25922	Inhibition (partial to complete)
<i>S. aureus</i> ATCC 25923	Inhibition (partial to complete)
<i>C. freundii</i> ATCC 8090	Growth of blue-green to blue colonies



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CHRMSA

Results: OK

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
Clinitest Reagent

Frequency of QC testing

Each new lot or shipment when received

Controls

Abnormal control from Urinalysis and distilled water

Procedure

Positive Control

1. Add 5 drops of abnormal control to a test tube.
2. Add 10 drops of distilled water to the tube.
3. Add 1 Clinitest tablet and allow reaction to proceed for 15 s.
4. Compare color of solution with color chart.

Negative Control

1. Add 15 drops of distilled water to a test tube.
2. Add 1 Clinitest tablet and allow reaction to proceed for 15 s.
3. Compare color of solution with color chart.

Expected Results

Abnormal control from Urinalysis = Positive (between trace and 3+)
Distilled water = Negative

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: CLNTST

Results: POS or NEG

Entering New Lots

MFG Code: BAYER

Department of Microbiology
QC Procedures
CLO Test

Frequency of QC testing

Each new lot or shipment when received

Control organism

Proteus mirabilis ATCC 35659

Procedure

1. Using a sterile inoculation needle, select fresh growth from weekly subculture stock of the control organism.
2. Peel back label and inoculate media. Replace label and mark with date and name of control organism.
3. Use a second CLO test that is not inoculated as the negative control.
4. Incubate both CLO tests in ambient atmosphere at 35-37 °C for 3 h.
5. Examine test reactions at 3 h and reincubate negative tests at room temperature for a full 24 h.

Expected Results

P. mirabilis 35659 = + (bright pink)



Uninoculated = - (no color change)



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CLO

Results: POS or NEG

Entering New Lots

MFG Code: KIMBER

Department of Microbiology
QC Procedures

Coagulase Plasma Reagent

Frequency of QC testing

Each new lot or shipment when opened

Control organisms

Staphylococcus aureus ATCC 25923

Staphylococcus epidermidis ATCC 12228

Procedure (slide test)

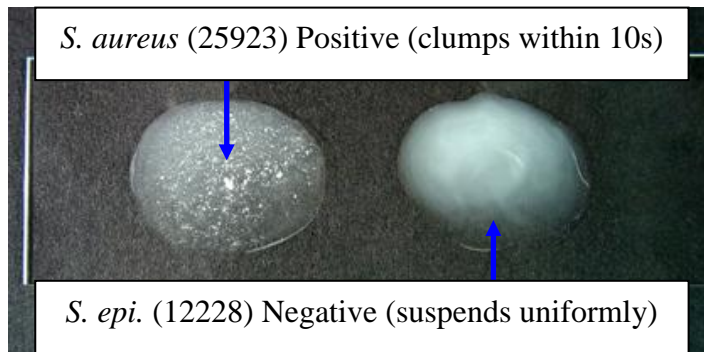
1. Place 1 drop of reagent on a glass slide.
2. With a wooden applicator, pick 1-2 isolated colonies from a pure culture.
3. Emulsify control organism into reagent and observe any clumping.

Procedure (tube test)

1. Using a culture that is less than 24 h old, inoculate the Coagulase Cryo™ by emulsifying one loop full (2-4 colonies) of bacteria into the liquid.
2. Incubate the inoculated tube at $35 \pm 2^\circ\text{C}$ without CO_2 for up to 4 h, and observe for clot formation hourly. Do not agitate the tube during observations. Gently tilt the vial to observe for clot formation. Negative tests at 4 h should be held at room temperature for a total of 24 h before reporting results.

Expected Results

Slide coagulase - Clumps that will not mix uniformly into coagulase plasma represent a positive slide coagulase test and are indicative of *S. aureus*. Colonies that mix smoothly into the plasma indicate a negative slide coagulase test (*S. epidermidis*).



Tube coagulase - Any degree of clotting of the plasma reagent before 24 h indicates a positive test (*S. aureus*). A flocculent or fibrous precipitate is not a true clot and should be regarded as negative. No clot formation by 24 h indicates a negative (*S. epidermidis*).

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: COAG and COAGTU

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Corn Meal Agar with Tween 80 Agar Medium

Frequency of QC testing

Each new lot or shipment

Control organism

Candida albicans ATCC 90028

Candida glabrata ATCC 15126

Procedure

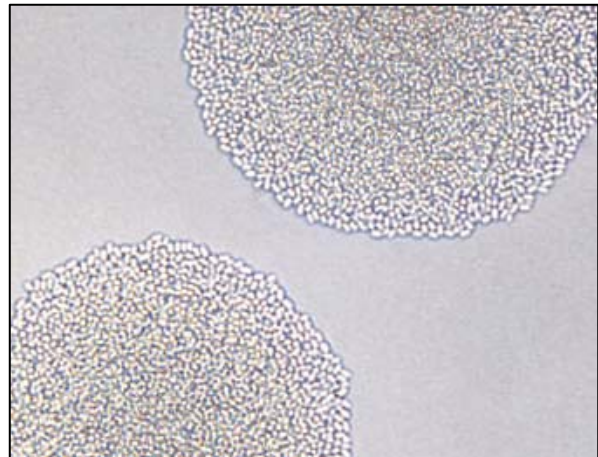
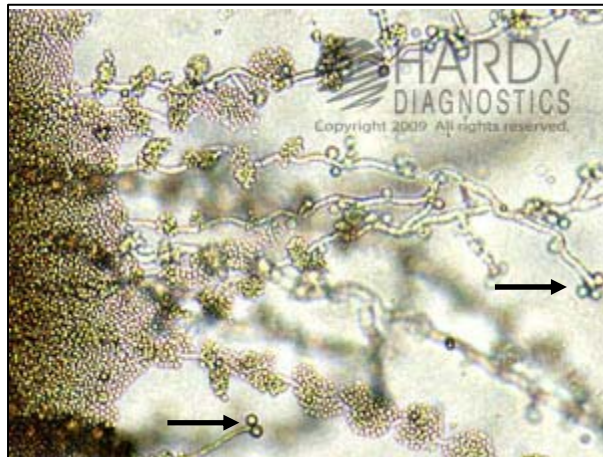
1. Using a sterile inoculating needle, harvest a portion of a young, actively growing yeast colony.
2. Make a streak on the agar surface without cutting into the agar. Make three or four streaks perpendicular to the first streak to dilute the inoculum.
3. Cover with a 22 x 22-mm coverslip.
4. Seal the plate with tape and incubate aerobically at room temperature ($25 \pm 2^\circ\text{C}$) for up to 3 d in the dark. Examine daily for growth.
5. Examine by placing the plate, without its lid, on the microscope stage and using the low power (X 100) and high-dry (X 400) objective. The most characteristic morphology is often found along the edge of the coverslip.

Expected Results

C. albicans 90028 - Growth; hyphae, budding cells, and chlamydospores seen

C. glabrata 15126 - Growth; no chlamydospores seen

Low power (X 100)



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CORN80

Results: OK

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures

Cryptococcus Antigen Kit

Frequency of QC Testing

External controls should be run with each new lot/shipment and every 30 d while in use. The internal control that is built into the test strip should be observed for each patient test.

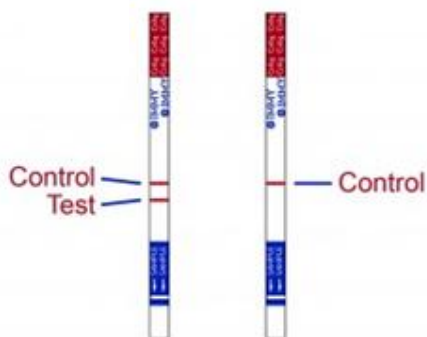
Controls

New lots and/or shipments should be checked using the same lot of control material that was used to check the old lot. This is accomplished by saving a specific lot of control materials from a shipment of kits and then using that lot of controls for testing subsequent lots/shipments that are received. The control materials may be used until the manufacturer's expiration date printed on the bottle. Document the control material lot number used for QC on the Package Insert Verification log.

Procedure

A positive control (CrAg Positive Control) can be evaluated by adding 1 drop of LF Specimen Diluent followed by 1 drop of CrAg Positive Control to a tube. A negative control can be evaluated by adding 2 drops of LF Specimen Diluent to a tube. Insert a test strip into the tubes, and read after 10 min. If external controls fail to produce the expected results, notify the supervisor and/or technical specialist. Lots and/or shipments that do not perform as expected cannot be used for patient testing. Document internal control results on the test log. Document the external control results on the log behind the test procedure and in LIS.

Expected Results



1 line = negative
2 lines = positive

Computer Entry of Results

Function: MQCE
Select: TESTQC
Category: UNSCHEDULED
Item Code: **CRYLFL**
Results: POS or NEG

Entering New Lots

MFG Code: IMMY

Department of Microbiology
QC Procedures

Crystal Anaerobe Identification Kit

Frequency of QC Testing

Each new lot or shipment, assigned

Control Organisms

Bacteroides fragilis ATCC 25285 (sub from stock kept in -70 °C freezer)

Bacteroides distasonis ATCC 8503 (sub from stock kept in -70 °C freezer)

Lactobacillus acidophilus ATCC 314 (sub from stock kept in -70 °C freezer)

Peptostreptococcus asaccharolyticus ATCC 29743 (sub from stock kept in -70 °C freezer)

Fusobacterium varium ATCC 27725 (sub from stock kept in -70 °C freezer)

Procedure

1. Inoculate panel with control organisms per procedure.
2. Prior to incubation, let *B. fragilis* (25285) panel remain at room temperature for 1 min (not more than 2 min).
3. Read and record reactions with the aid of the viewer and color reaction chart.
4. If any of the wells, except 1F, are positive DO NOT USE PANELS from this lot and notify supervisor.
5. If wells are negative, incubate all of the panels for 4 h at 35-37 °C. Read panel with panel viewer and record reactions on the report pad.

Expected Results

See Table 5 of kit insert for expected reactions for control organisms.

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: CRSTQC

Results: OK

Entering New Lots

MFG Code: BD

Department of Microbiology
QC Procedures
***E. coli* O157 Latex Kit**

Frequency of QC Testing

Each new kit opened

Control Organisms

Kit controls

Procedure

1. Place 1 drop of *E. coli* O157 Latex Reagent on to a test circle on one of the test cards provided.
2. In a separate circle, add 1 drop of Negative Control Latex Reagent.
3. To both test circles, add 1 drop each of the Positive Control Antigen.
4. Mix reagents in each test circle with a separate mixing stick.
5. Rock card gently and examine for agglutination over a 2 min period.

Expected Results

O157 Latex Reagent + Positive Control Antigen = Visible agglutination within 2 min

Negative Control Latex Reagent + Positive Control Antigen = No agglutination

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: ECO157

Results: POS or NEG

Entering New Lots

MFG Code: PROLAB

Department of Microbiology
QC Procedures

Enteric Bacterial PCR BD MAX Kit

Frequency of QC Testing

Each new lot or shipment and every 30 d while in use.

Control Organisms

- Positive External Control: Pooled, diluted suspensions of *Campylobacter jejuni* ATCC 33291, *E. coli* O157:H7 ATCC 35150, *Salmonella enteritidis* ATCC 14028, and *Shigella sonnei* ATCC 9290.
- Negative External Control: Saline.

Procedure and Expected Results

External Controls

1. Suspensions of the control strains should be prepared in saline to a turbidity of 0.5 McFarland ($\sim 1.0 \times 10^8$ CFU/mL) from isolated colonies. Dilute the *Salmonella*, *Shigella*, and *E. coli* organisms 1:10 and the *Campylobacter* 1:100. Dilute each suspension 2:5. Combine equal portions of each control suspension to obtain a final concentration of $\sim 1.0 \times 10^6$ CFU/mL (for *Salmonella*, *Shigella*, and *E. coli*) and $\sim 1.0 \times 10^5$ CFU/mL (for *Campylobacter*).
2. Suspensions may be frozen in aliquots at -70 °C and thawed prior to use.
3. Dip a separate 10- μ L loop into each bacterial suspension and inoculate the sample buffer tubes.
4. Follow testing protocol outlined in the BD MAX™ Bacterial Enteric Panel Procedure.
5. All quality control results should be entered into the LIS. Notify supervisor if results are not as expected.

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MAXBEN

Results for kit QC: NEG, POS

Entering New Lots

MFG Code: BD

Item: MAXBEN

Department of Microbiology
QC Procedures

Rapid ESBL for Blood Cultures

Frequency of QC testing

Each day of patient testing.

Control organisms

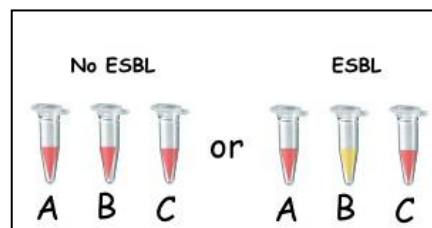
Control material consists of blood cultures spiked with 0.1 mL of a 0.5 McFarland suspension of each control strain and incubated overnight. New control cultures should be inoculated on Monday of each week.

- *E. coli* ATCC 25922 (ESBL-negative)
- *E. coli* (ESBL-positive) clinical isolate previously characterized by CLSI ESBL disk confirmation test. Do not use *K. pneumoniae* ATCC 700603. This strain contains an uncommon ESBL phenotype that reacts weakly with the rapid ESBL assay.

Procedure

1. Retrieve a set of Reagent A, B, and C from the -70°C freezer for each control and patient sample.
2. Under a biosafety hood, transfer 1.5 mL of a positive blood culture to a 2-mL screw-cap microcentrifuge tube using a 3-cc syringe with a 20-gauge blunt transfer needle.
3. Add 150 µL of Triton X-100 Surfact-Amps® Detergent.
4. Cap the tube, and vortex for 30 s.
5. Let tube sit for 5 min.
6. Centrifuge at 13,000 x *g* for 2 min.
7. Under a biosafety hood, use a fine-tip transfer pipette to remove and discard the supernatant in the biohazardous waste.
8. Suspend the pellet in 1,000 µL of distilled water by mixing up and down with the pipette.
9. Centrifuge at 13,000 x *g* for 2 min.
10. Under a biosafety hood, use a fine-tip transfer pipette to remove and discard the supernatant in the biohazardous waste.
11. Suspend the pellet in 310 µL of B-PER® II, Bacterial Protein Extraction Reagent by mixing up and down with the pipette.
12. Transfer 100 µL of the bacterial extraction to each tube of Reagent A, B, and C.
13. Incubate the tubes in a heat block at 37°C for 30 min.
14. Examine the color of the reagents in each tube

Expected Results



Documentation of Results

Results should be documented on the QC log rather than in the computer.

Department of Microbiology
QC Procedures
Esculin Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

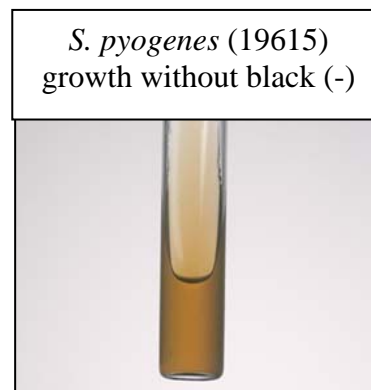
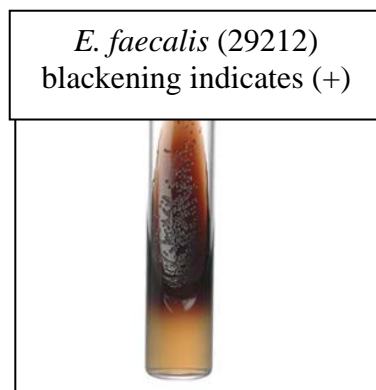
Enterococcus faecalis ATCC 29212

Streptococcus pyogenes ATCC 19615

Procedure

1. Label 2 esculin agar slants with date and each of the control organism names.
2. Using a sterile inoculating loop, select and remove several isolated colonies of control organism and inoculate respective slant.
3. Incubate slants with lids loosened in an ambient atmosphere at 35 °C for 24-48 h.
Observe slants for blackening of the agar indicating esculin hydrolysis.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: ESCSL

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures
Fecal Fat (Sudan III) Stain

Frequency of QC testing

With each batch of specimens tested.

Controls

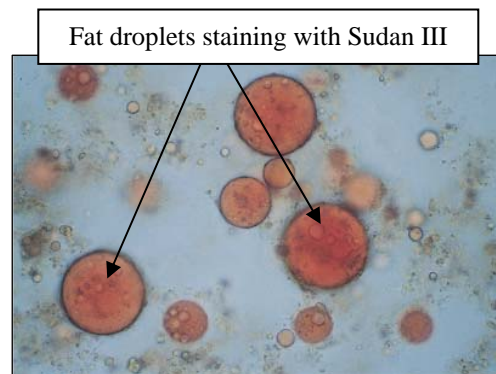
Mayonnaise: increased neutral and total fat

Soap shavings: increased total fat

Procedure

1. Prepare smears using controls in the same manner as patient testing (see procedure manual).
2. Examine preparation under 40X for large orange-red droplets.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: FATST

Results: MAYON: POS, MAYOT: POS, SOAPN: NEG, AND SOAPT: POS

Entering New Lots

MFG Code: SHM

**Department of Microbiology
QC Procedures**

FilmArray Blood Culture ID Panel

Frequency of QC Testing

Each new lot or shipment and every 30 d while in use. Controls should be tested on alternate instruments each time in order to correlate results from each instrument.

Controls

External control materials are prepared in-house by pooling suspensions of ATCC control strains or previously characterized clinical isolates. A suspension equivalent to a 3 McFarland turbidity standard is prepared for each test strain. The multi-target controls are created by combining equal amounts of each suspension into two separate pools. The control materials are stored in 200 µL aliquots at -70°C.

Procedure and Expected Results

Quality Control testing is performed in the same manner as for clinical specimens, except that 0.1 mL of the control material is used instead of a positive blood culture. The table below lists the targets in each set and the expected results when tested on BCID assay. A *Neisseria meningitidis* strain is not included in either of the control pools for safety reasons.

Target	Strain	BC Multi 1	BC Multi 2
<i>Acinetobacter baumannii</i>	ATCC 19606	Negative	Positive
<i>Candida albicans</i>	ATCC 90028	Positive	Negative
<i>Candida glabrata</i>	ATCC 15126	Positive	Negative
<i>Candida krusei</i>	ATCC 14243	Positive	Negative
<i>Candida parapsilosis</i>	ATCC 22019	Positive	Negative
<i>Candida tropicalis</i>	ATCC 750	Positive	Negative
<i>Enterobacter cloacae</i>	ATCC 13047	Negative	Positive
<i>Enterococcus</i>	ATCC 51299	Positive	Negative
<i>Escherichia coli</i>	ATCC 25922	Negative	Positive
<i>Haemophilus influenzae</i>	ATCC 35056	Negative	Positive
<i>Klebsiella oxytoca</i>	Clinical strain	Negative	Positive
<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	Negative	Positive
<i>Listeria monocytogenes</i>	Clinical strain	Positive	Negative
<i>Neisseria meningitidis</i>	Not included	Negative	Negative
<i>Proteus</i>	ATCC 35659	Negative	Positive
<i>Pseudomonas aeruginosa</i>	ATCC 27853	Negative	Positive
<i>Serratia marcescens</i>	ATCC 8100	Negative	Positive
<i>Staphylococcus aureus</i>	ATCC 43300	Positive	Negative
<i>Streptococcus agalacticae</i>	ATCC 12386	Positive	Negative
<i>Streptococcus pneumoniae</i>	ATCC 49619	Positive	Negative
<i>Streptococcus pyogenes</i>	ATCC 19615	Positive	Negative

Computer Entry of Results

Function: MQCE
 Select: PCRQC
 Category: UNSCHEDULED
 Item Code: FILMBL
 Results for kit QC: PASS/FAIL

Entering New Lots

MFG Code: BIOFR

**Department of Microbiology
QC Procedures**

FilmArray Respiratory Panel

Frequency of QC Testing

Each new lot or shipment and every 30 d while in use. Controls should be tested on alternate instruments each time in order to correlate results from each instrument.

Controls

ZeptoMetrix NATrol™ RP Multimarker External Run Controls (NATRPC-BIO) in refrigerator.

Procedure and Expected Results

Each control pack contains 3 x 0.6 mL vials of RP Multi 1 and 3 x 0.6 mL vials of RP Multi 2. Quality Control testing using the NATrol™ RP Multimarker is performed in the same manner as for clinical specimens, except that 0.3 mL of the control material is used instead of a specimen in VTM. Control materials should be vortexed for 30 s just prior to use. The table below lists the respiratory targets and expected results.

Target		RP Multi 1	RP Multi 2
Adenovirus		Positive	Negative
Coronavirus 229E		Negative	Positive
Coronavirus HKU1		Negative	Positive
Coronavirus NL63		Negative	Positive
Coronavirus OC43		Negative	Positive
Human Metapneumovirus		Positive	Negative
Human Rhinovirus/ Enterovirus	Entero 1	Positive	Negative
	Entero 2	Positive	Negative
	HRV1	Positive	Negative
	HRV2	Positive	Negative
	HRV3	Positive	Negative
	HRV4	Positive	Negative
Influenza AH1-2009	Flu A-H1-2009	Positive	Negative
Influenza AH1	Flu A-H1-pan	Positive	Positive
Influenza AH3	Flu A-H3	Positive	Negative
	Flu A-pan1	Positive	Positive
	Flu A-pan2	Positive	Positive
Influenza B		Negative	Positive
Parainfluenza Virus 1		Positive	Negative
Parainfluenza Virus 2		Negative	Positive
Parainfluenza Virus 3		Negative	Positive
Parainfluenza Virus 4		Positive	Negative
Respiratory Syncytial Virus		Negative	Positive
<i>Bordetella pertussis</i>		Negative	Positive
<i>Chlamydomphila pneumoniae</i>		Positive	Negative
<i>Mycoplasma pneumoniae</i>		Positive	Negative

Computer Entry of Results

Function: MQCE

Select: PCRQC

Category: UNSCHEDULED

Item Code: FILMR

Results for kit QC: PASS/FAIL

Entering New Lots

MFG Code: BIOFR

Department of Microbiology
QC Procedures
GBS Detect Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Strep agalactiae ATCC 13813

Enterococcus faecalis ATCC 29212

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:100 in normal saline.
3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Incubate plates at 35 ± 2 °C in an aerobic atmosphere.

Expected Results

Control strain	Expected Results
<i>S. agalactiae</i> ATCC 13813	Growth; beta-hemolysis
<i>E. faecalis</i> ATCC 29212	Partial to complete inhibition



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: GBS

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

On individual plates, the lot number follows the product code, A300.

Do not confuse the plate number with the lot number.

Department of Microbiology
QC Procedures
GBS PCR BD MAX Kit

Frequency of QC Testing

Each new lot or shipment and every 30 d while in use.

Control Organisms

Streptococcus agalactiae ATCC 13813

Procedure and Expected Results

External Controls

1. *Streptococcus agalactiae* ATCC 13813 should be cultured in Lim Broth for ≥ 18 h at 35 ± 2 °C.
2. Broth may be frozen in aliquots at -70 °C and thawed prior to use.
3. Follow testing protocol outlined in the BD MAX™ GBS Assay Procedure.
4. All quality control results should be entered into the LIS. Notify supervisor if results are not as expected.

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MAXGBS

Results for kit QC: NEG, POS

Entering New Lots

MFG Code: BD

Item: MAXGBS

Department of Microbiology
QC Procedures

Germ Tube Plasma Reagent

Frequency of QC testing

Weekly and each new lot

Control organisms

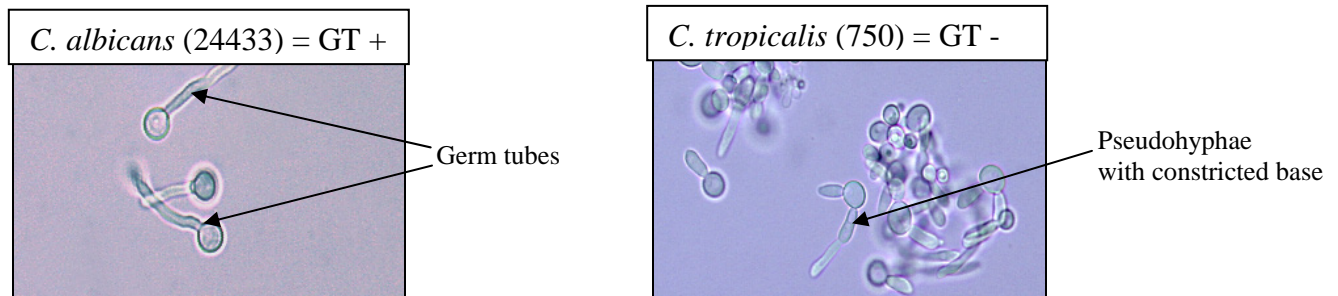
Candida albicans ATCC 24433

Candida tropicalis ATCC 750

Procedure

1. Label 2 glass test tubes.
2. Aliquot about 0.5 mL of germ tube plasma into each tube.
3. Select an isolated colony of QC organism and remove with a wooden applicator.
Suspend the inoculum in the plasma.
4. Incubate the test tubes at 35 °C for 2 h.
5. Prepare wet mounts on each suspension and examine on low power for GT formation.
Confirm results on high power to distinguish GT from pseudohyphae with constrictions.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: Weekly under MEDIA

Otherwise under UNSCHEDULED

Item Code: GERMTU

Results: POS or NEG

Entering New Lots

MFG Code: SHM

Department of Microbiology
QC Procedures
Gram Stain

Frequency of QC testing

Weekly and each new lot

Control organisms

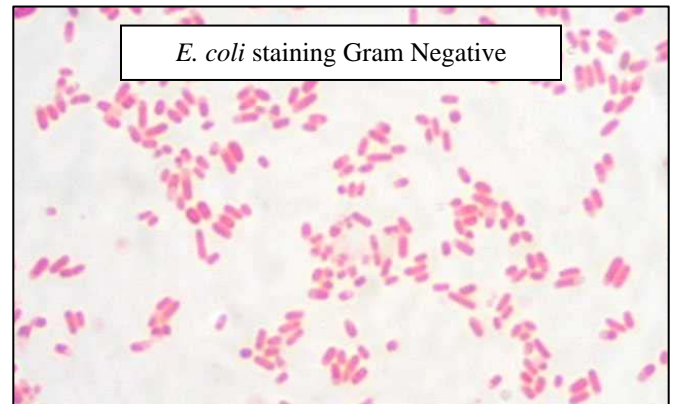
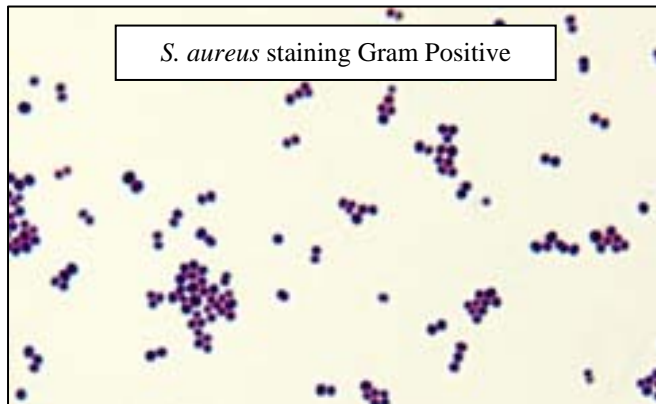
Positive control slide: smear of *Staphylococcus aureus* ATCC 25923

Negative control slide: smear of *E. coli* ATCC 25922

Procedure

1. Flood dry smears with crystal violet for 1 min.
2. Drain off stain and gently rinse with water.
3. Flood smear with Gram's iodine for 1 min.
4. Drain off iodine and gently rinse with water.
5. Decolorize with acetone-alcohol until the purple stain no longer runs.
6. Rinse with water.
7. Flood smear with safranin for 1 min.
8. Rinse off stain with water and air dry (slide dryer)
9. Examine with light microscope on 100X objective for appropriate staining reactions.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: Weekly under STAINS

Otherwise under UNSCHEDULED

Item Codes: GRAMST

Results: POS or NEG

Entering New Lots

MFG Code: BD

Department of Microbiology
QC Procedures

Haemophilus Test Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Haemophilus influenzae ATCC 49247

Procedure

1. Prepare a bacterial suspension of the control organism from overnight growth. The suspension should be equivalent to a 0.5 McFarland turbidity.
2. Use the bacterial suspension to inoculate the agar surface as outlined in disk diffusion procedure.
3. Apply antibiotic disks and place in CO₂ incubator within 15 min.
4. Incubate at 35° C for 16-18 h and then measure zone diameters of each antibiotic.

Expected Results

Ampicillin (AM) 13-21 mm

Ceftriaxone (CRO) 31-39 mm

Imipenem (IMP) 21-29 mm

Trimethoprim-sulfamethoxazole (SXT) 24-32 mm

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: HTMQC

Results: Zone sizes

Entering New Lots

MFG Code: BBL

Rapid HIV Kit (Determine HIV1&2 Ag/Ab Combo)

Frequency of QC Testing

External controls are run with each new lot or shipment when received and every 30 d, while in use. Internal controls must be read and documented for each test.

Controls

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls are available, separate from the kit, for use with the assay. Control material should be stored at 2-8°C and used up to the expiration date.

Procedure

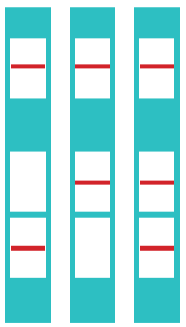

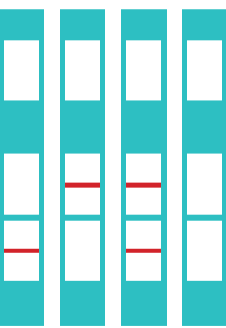
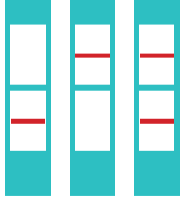

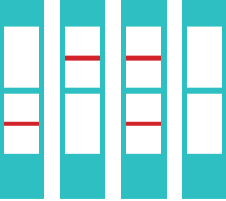



External Quality Control

1. Use one test device for each of the four controls.
2. Using a pipette, apply 50 µL of control to the sample pad (marked by the arrow symbol). Do not add chase buffer.
3. Read the test result between 20 and 30 min after the addition of the sample. Do not read test results after 30 min.

Internal Quality Control

A pink/red colored line appearing in the control area is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the results area is considered an internal negative control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.

Expected Results

Result Key			
Line	Reactive	Nonreactive	Invalid
Control			
Ag			
Ab			

- Nonreactive Control (One Line – Control Line)**
- HIV-1 p24 Antigen Control (Two Lines - Control and Ag Line)**
- HIV-1 Reactive Control (Two Lines - Control and Ab Line)**
- HIV-2 Reactive Control (Two Lines - Control and Ab Line)**

Documenting QC

Record the internal control on the test log and external QC in LIS

Computer Entry of Results

Function: MQCE
 Select: TESTQC
 Category: UNSCHEDULED
 Item Code: HVABAG
 Results: OK

Entering New Lots

MFG Code: ALERE

Department of Microbiology
QC Procedures
ImmunoCard STAT! EHEC Kit

Frequency of QC Testing

Each new lot or shipment when received (or with each new untrained operator)

Controls

Kit controls

Procedure

External Quality Control

1. Bring all test devices and reagents to room temperature (20-25° C) before testing.
2. Use one test device each for a positive and negative control.
3. Remove the test device from its foil pouch and label with the control to be tested.
4. Add exactly 5 drops of the Positive Control reagent to the sample port of a device marked for the positive control.
5. Add exactly 5 drops of the Sample Diluent to the sample port of a device marked for the negative control.
6. Incubate the test at 20 – 25° C for 20 min. Read the results within 1 min after the end of incubation.

Internal Quality Control

Internal controls are contained within the test strip and therefore are evaluated with each test. A pink-red band appearing at the Control line serves as a procedural control and indicates the test has been performed correctly, that proper flow occurred and that the test reagents were active at the time of use. A clean background around the Control or Test lines also serves as a procedural control. Control or test lines that are obscured by heavy background color may invalidate the test and may be an indication of reagent deterioration, use of an inappropriate sample or improper test performance.

Expected Results

The positive control should yield pink-red bands in both Toxin 1 and Toxin 2 test line positions. The negative control should not yield bands in either of the Toxin 1 or Toxin 2 test line positions. A pink-red band must be present at the internal control test line for the results to be valid.



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: EHEC

Results: POS, POS, NEG, NEG

Entering New Lots

MFG Code: MERID

Department of Microbiology
QC Procedures
Spot Indole Reagent

Frequency of QC testing

Each new lot or shipment when received

Control organisms

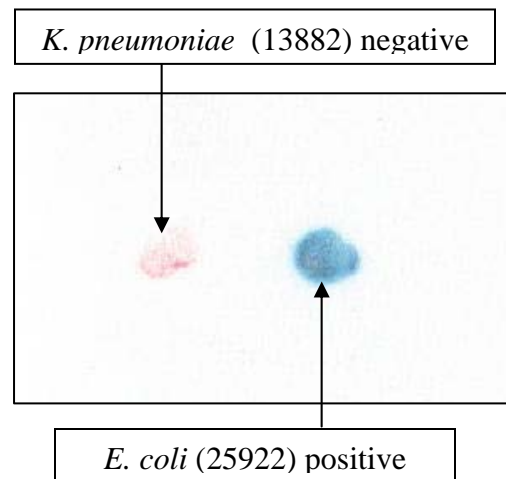
E. coli ATCC 25922

Klebsiella pneumoniae ATCC 13882

Procedure

1. Saturate a small piece of filter paper with reagent.
2. Using a wooden applicator, select an isolated colony from control organism and spread inoculum onto saturated filter paper.
3. Repeat testing on other control organism.
3. Observe for development of blue/green color within 30 s, indicating a positive reaction.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: INDOLE

Results: POS or NEG

Entering New Lots

MFG Code: PML

Department of Microbiology
QC Procedures
Kinyoun Stain for AFB

Frequency of QC testing

Each day test is performed

Control organisms

Positive control slide (previous positive patient specimen)

Negative control slide (E. coli)

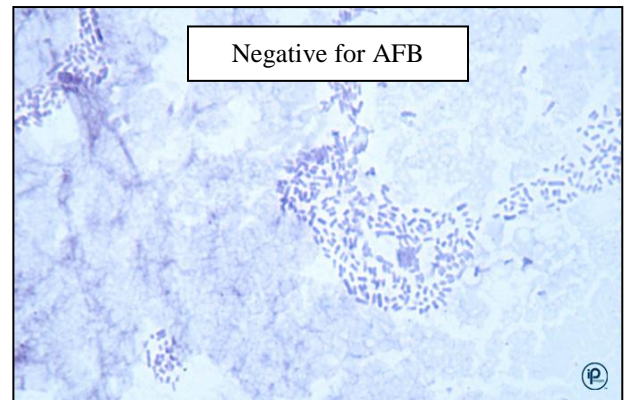
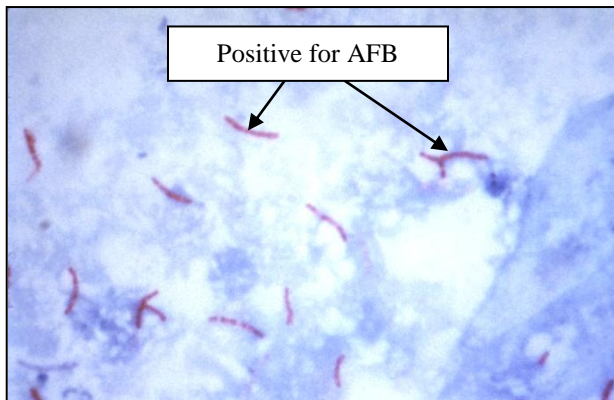
Procedure

1. Flood slides with carbol fuchsin and stain for 5 min.
2. Rinse slides gently with tap water.
3. Decolorize smears using 3% acid alcohol (HCL) until runoff is clear.
4. Rinse gently with tap water.
5. Counterstain smear with methylene blue for 1 min.
6. Rinse with tap water and air dry.
7. Examine smear under oil immersion for appropriate staining reaction.

Expected Results

Positive control: red bacilli against a blue background

Negative control: no red organisms



Computer Entry of Results

Function: MQCE

Select: **TBQC**

Category: UNSCHEDULED

Item Codes: KINST

Results: POS or NEG

Entering New Lots

MFG Code: SHM

Department of Microbiology
QC Procedures
Lacto-Phenol Cotton Blue

Frequency of QC testing

Each new lot or shipment when received

Control organism

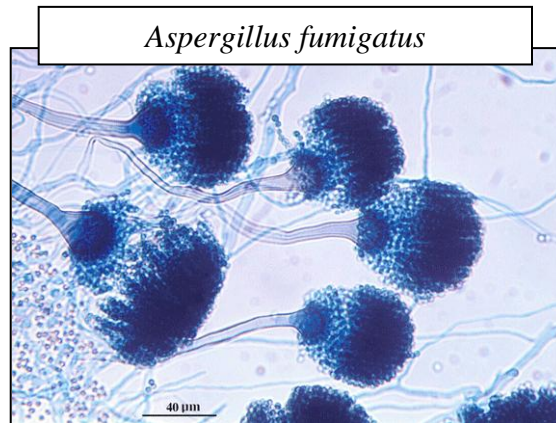
Mold isolate

Procedure

Perform LPCB prep of mold isolate and examine microscopically for intended reactivity.

Expected Results

Hyphae absorb LPCB and demonstrate deep blue staining of the hyphae walls and septae. Interior of hyphae should stain pale blue.



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: LCB

Results: OK

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures

LAP (Leucine Aminopeptidase) Disks

Frequency of QC testing

Each new lot or shipment, when received

Control organisms

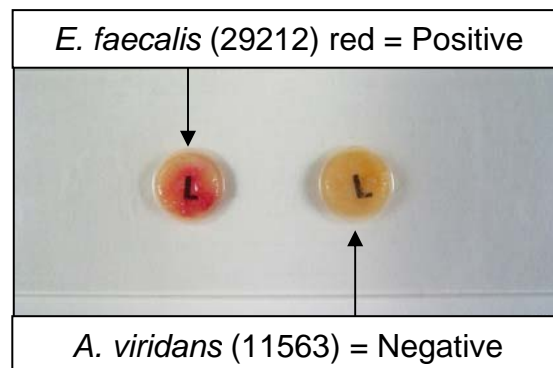
Enterococcus faecalis ATCC 29212

Aerococcus viridans ATCC 11563

Procedure

1. Dispense 2 disks onto a glass slide.
2. Moisten each disk with 1 drop of water.
3. Smear 5-10 well-isolated colonies of control organism onto separate disks using wooden applicators.
4. Incubate at room temperature for 5 min.
5. Add one drop of color developer to each disk and examine for pink to red color change within 1 min indicating a positive reaction.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: LAP

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures
Legionella DFA Stain

Frequency of QC testing

Each time of use

Control s

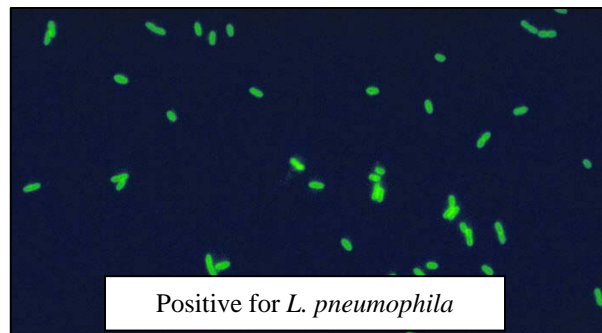
Positive control slide: *L. pneumophila* Antigen

Negative control slide: *E. coli* ATCC 25922

Procedure

1. Control slides are prepared in batches and stored at -20°C . See procedure for preparation of control smears. Allow slides to reach RT.
2. Dispense 1 drop of reagent onto each smear.
3. Place slides in a moist chamber and incubate for 30 min at $35-37^{\circ}\text{C}$.
4. Rinse reagent off slides with a gentle stream of distilled water around the outside of the well.
5. Air dry slides.
6. Add 1-2 drops of mounting medium to the slide and apply a coverslip.
7. Scan each smear with 20X. If fluorescent speckles are observed, use 100X to confirm the cellular morphology consistent with *Legionella*.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: LEGST

Results: POS or NEG

Entering New Lots

MFG Code: BIORAD

Department of Microbiology
QC Procedures
MacConkey Sorbitol Agar

Frequency of QC testing

Each new lot or shipment when received

Control organisms

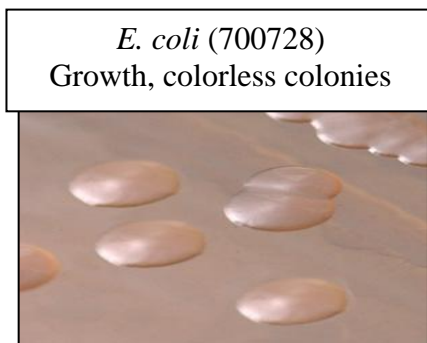
E. coli ATCC 700728

E. coli ATCC 25922

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar sub plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:10 in normal saline.
3. Using a 10 μ L loop (large urine loop), inoculate the agar and streak for isolation.
4. Incubate media in an ambient atmosphere at 35 °C for 24 h.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MACSRB

Results: OK

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures

Lysozyme Broth Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Nocardia species

Streptomyces species

Procedure

1. Inoculate Lysozyme and Control broth tubes with control organisms as outlined in the Lysozyme Broth procedure.
2. Incubate tubes at 35 °C up to 4 weeks and observe for turbidity twice a week.

Expected Results

Nocardia species: Growth in both the Lysozyme Broth and the Control Broth

Streptomyces species: Growth in Control Broth only

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: LYSOBR, LYSOCB

Results: POS or NEG

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures
Modified Hodge Test

Frequency of QC testing

Each day clinical isolates are tested

Control organisms

K. pneumoniae ATCC BAA-1705

K. pneumoniae ATCC BAA-1706

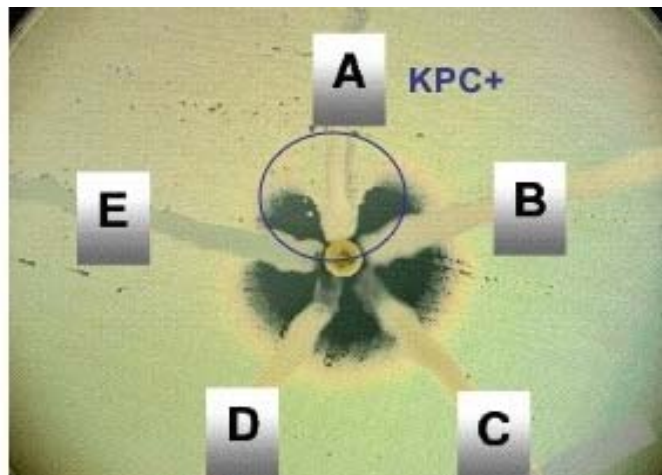
Procedure

1. Prepare a 0.5 McFarland suspension of *E. coli* ATCC 25922.
2. Dilute the suspension of *E. coli* ATCC 25922 1:10 with sterile saline.
3. Using a sterile swab, streak the diluted suspension on the surface of a MHA plate for confluent growth.
4. Allow the agar surface to dry briefly, and place a 10- μ g meropenem disk in the center of the plate.
5. Using a sterile 10- μ l inoculation loop or swab, pick 3-5 colonies of the QC organism grown on a blood agar plate and streak in a straight line out from the edge of the disk. The streak should be at least 20-25 mm in length. Three organisms may be tested with each disk simultaneously on a small MHA plate. Be sure to label the plate carefully so that the test and QC isolates may be correctly identified later.
6. Incubate the plate for 16-20 h at 35 ± 2 °C; ambient air.

Expected Results

K. pneumoniae ATCC BAA-1705
POS as indicated by the distorted
intersection (see A in figure below)

K. pneumoniae ATCC BAA-1706
NEG as indicated by no intersection
distortion (see B-E)



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: HODGE

Results: POS, NEG

Entering New Lots

MFG Code: BD

Department of Microbiology
QC Procedures

Modified Kinyoun Stain for *Cryptosporidium/Cyclospora/Isospora*

Frequency of QC testing

Each day test is performed

Control organisms

Positive control slide with *Cryptosporidium* oocysts

Negative control slide made from negative patient

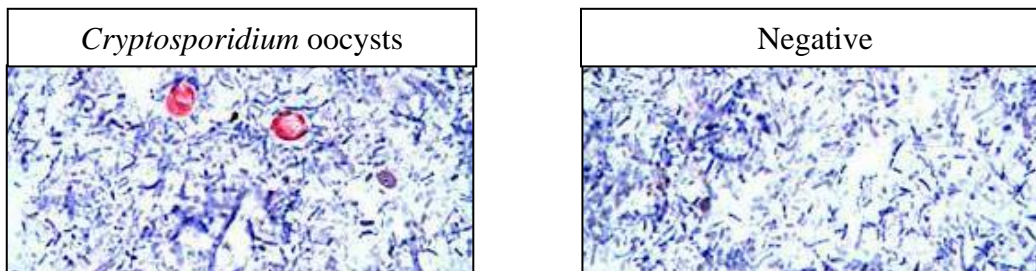
Procedure

1. Label slides "Cryptosporidium control" and "Negative control."
2. Control slides are prepared by placing a small drop of respective fecal concentrate on each slide and spreading over an area about the size of a nickel. Heat-fix smears on slide warmer. Slides may be prepared in batches ahead of time or purchased from a commercial source.
3. Place controls with patient smear(s) on the staining rack in the sink.
4. Flood the smears with Kinyoun's carbol-fuchsin, and let it stain for 5 min.
5. Rinse slide briefly (3 to 5 s) with 50% ethanol.
6. Rinse slide with running tap water.
7. Decolorize the slides with 1% sulfuric acid for 2 min or until no more color runs.
8. Rinse the slide with water and drain.
9. Counterstain by flooding smears with methylene blue for 30 to 60 s.
10. Rinse slide with water and air dry.
11. Examine smear under 10X objective with a light microscope for the presence of oocysts. Confirm organism morphology and staining characteristics by examining smear on oil immersion.

Expected Results

Positive control: Red oocysts 4-5 μm in size with a blue background

Negative control: No red-staining organisms resembling *Cryptosporidium*



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: CRYPST

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Modified Kinyoun Stain for *Nocardia*

Frequency of QC testing

Each day test is performed

Control organisms

Nocardia farcinica ATCC 3308

Streptomyces albus ATCC 17900

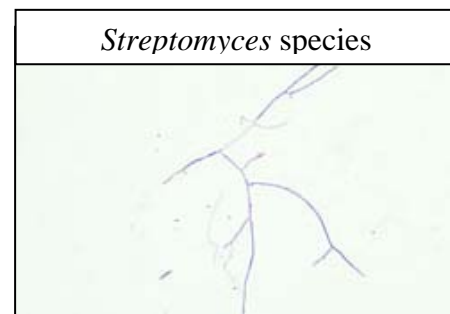
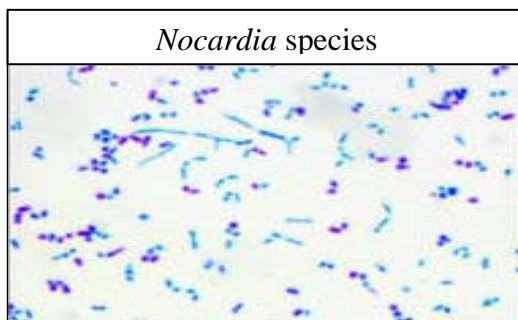
Procedure

1. Control slides can be prepared from suspensions of the control organisms grown on Lowenstein-Jensen or 7H11 agar.
2. Label 2 glass slides with date and name of respective control organism.
3. Prepare a 0.5 McFarland suspension of each organism in sterile saline and use a 0.01 mL calibrated loop to prepare the smears. Do not prepare smears too thick.
4. Heat-fix the control slides and stain simultaneously with patient smears.
5. Place patient smear(s) and control slides on a staining rack.
6. Flood the smears with Kinyoun carbol fuchsin and allow staining for 5 min.
7. Pour off excess stain.
8. Briefly rinse the smears for 3-5 s with 50% alcohol and immediately rinse with water.
9. Decolorize smears with 1% aqueous sulfuric acid for 2-3 min.
10. Rinse smears with water.
11. Flood smears with methylene blue and counterstain for 30-60 s.
12. Rinse smears with water, dry, and examine under oil immersion.

Expected Results

Nocardia: some cells should retain carbol fuchsin (red) while other will appear blue

Streptomyces: cells should not retain carbol fuchsin but will stain blue with counterstain



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: MAFBST

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures

Modified Thayer Martin Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

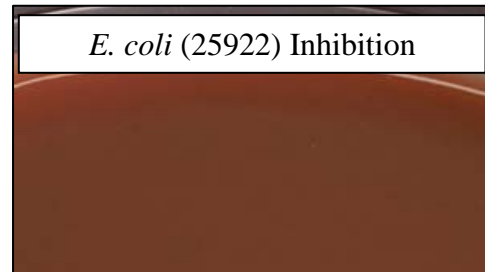
Neisseria gonorrhoeae ATCC 43069

E. coli ATCC 25922

Procedure

1. Make a basic cell suspension directly from growth of a fresh agar sub plate and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspension 1:10 in normal saline.
3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Incubate media in CO₂ atmosphere for 24-48 h at 35 °C.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MTM (whole plate), MTMCHO (split plate)

Results: POS or NEG

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures

Moeller Ornithine & Lysine Decarboxylase, & Arginine Dihydrolase Broth Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Klebsiella pneumoniae ATCC 13882

Enterobacter cloacae ATCC 13047

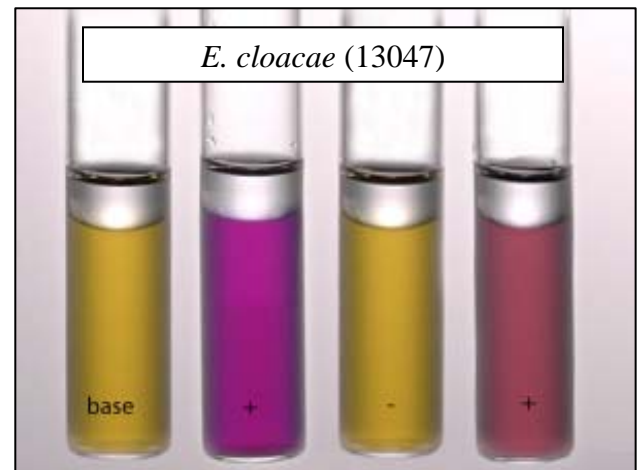
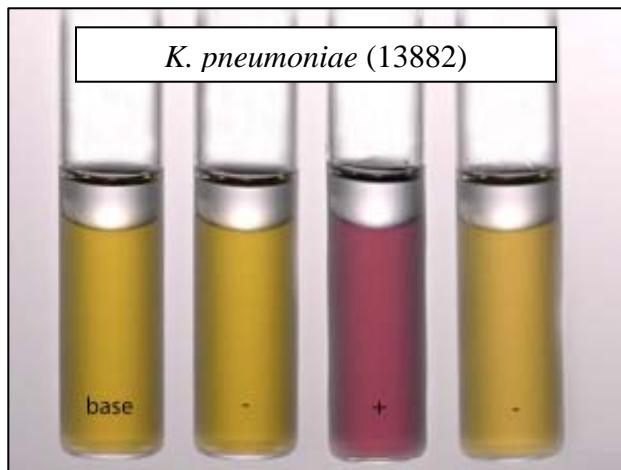
Procedure

1. Label tubes of broth with date and each of the control organism names.
2. Using a sterile inoculating loop, select one colony of the control organism and transfer to respective tube.
3. After all tubes have been inoculated, overlay the broth with approximately 1 mL of sterile mineral oil.
4. Incubate media in an ambient atmosphere at 35 °C for 18-24 h.

Expected Results

(-) = yellow or no change and (+) = purple

Organism	Base	Ornithine	Lysine	Arginine
<i>K. pneumoniae</i> (13882)	-	-	+	-
<i>E. cloacae</i> (13047)	-	+	-	+



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: DECARB, ORNITH, LYSINE, ARGIN

Results: POS or NEG

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures

Mono (Acceava Mono II) Kit

Frequency of QC Testing

Each new lot or shipment when received (or with each new untrained operator)

Control s

Kit reagents (positive and negative controls)

Procedure

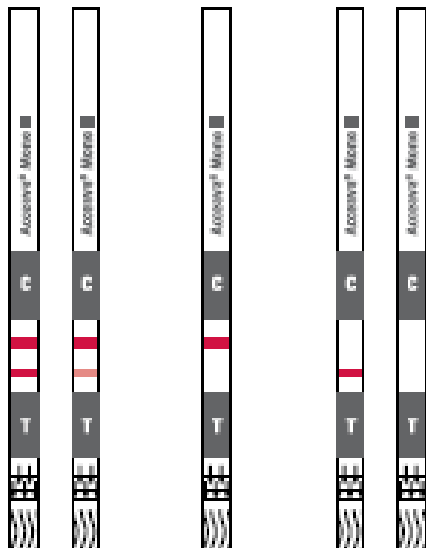
External Quality Control

1. In two Test Tubes provided in kit, add one free falling drop of positive control to one tube one drop of negative control to the other
2. Add one drop of Sample Buffer and tap bottom of tube to mix.
3. Remove two Test Strips from the container. Place one Test Strip into each control tube (the absorbent end in first) and leave the Test Strip in the tube.
4. Read results at 5 minutes.

Internal Quality Control

1. The test provides two levels of internal procedural controls with each test procedure.
 - a. The red Control Line is an internal positive procedural control. The Test Stick must absorb the proper amount of test material and be working properly for the red Control Line to appear.
 - b. A clear background is an internal negative procedural control. If the test has been performed correctly and the Test Stick is working properly, the background will clear to give a discernible result.

Expected Results



Positive

Negative

Invalid

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MONOQC

Results: POS and NEG

Entering New Lots

MFG Code: INV

Department of Microbiology
QC Procedures

Moraxella catarrhalis Disks

Frequency of QC testing

Each new lot or shipment, when received

Control organisms

Moraxella catarrhalis ATCC 25238

Neisseria lactamica ATCC 23970

Procedure

1. Place 2 disks on a glass slide.
2. Smear several colonies of pure control isolates onto separate disks using a wooden applicator.
3. Observe for a blue-green color development within 2 min to indicate a positive reaction.

Expected Results

M. catarrhalis (25238)
Positive (blue-green color)

N. lactamica (23970)
Negative (no color change)



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MCAT

Results: POS or NEG

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures
MRSA XT PCR BD MAX Kit

Frequency of QC Testing

Each new lot or shipment and every 30 d while in use.

Control Organisms

Staphylococcus aureus ATCC 43300 (MRSA)

Staphylococcus aureus ATCC 25923 (MSSA)

Procedure and Expected Results

External Controls

1. Suspensions of the control strains should be prepared in saline to a turbidity of 0.5 McFarland ($\sim 1.0 \times 10^8$ CFU/mL) from isolated colonies and subsequently diluted with saline to obtain a final concentration of ($\sim 1.0 \times 10^4$ CFU/mL).
2. Suspensions may be frozen in aliquots at -70 °C and thawed prior to use.
3. Use swabs to dip into the control suspensions.
4. Follow testing protocol outlined in the BD MAX™ MRSA XT Assay Procedure.
5. All quality control results should be entered into the LIS. Notify supervisor if results are not as expected.

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MAXMRS

Results for kit QC: NEG, POS

Entering New Lots

MFG Code: BD

Item: MAXMRS

Department of Microbiology
QC Procedures

Mueller Hinton Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Pseudomonas aeruginosa ATCC 27853

Procedure

1. Prepare a bacterial suspension (using BBL Prompt) of the control organism from overnight growth. Alternatively, prepare a suspension by inoculating 3-5 colonies of the weekly stock into sterile TSB. Incubate for several hours to achieve a suspension equivalent to a 0.5 McFarland standard.
2. Use the bacterial suspension to inoculate the Mueller Hinton agar surface as outlined in disk diffusion procedure.
3. Apply antibiotic disks and place in aerobic (O₂) incubator within 15 min.
4. Incubate in ambient atmosphere at 35 °C for 16-18 h and then measure zone diameters of each antibiotic.

Expected Results

Aztreonam (ATM) 23-29 mm
Ceftazidime (CAZ) 22-29 mm
Ciprofloxacin (CIP) 25-33 mm
Gentamicin (GM) 16-21 mm
Imipenem (IPM) 20-28 mm
Levofloxacin (LVX) 19-26 mm
Piperacillin-Tazobactam (TZP) 25-33 mm
Tobramycin (NN) 19-25 mm

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MHQC

Results: Zone sizes

Entering New Lots

MFG Code: BBL or REMEL

Department of Microbiology
QC Procedures

Mueller Hinton Agar w/5% Sheep Blood

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Streptococcus pneumoniae ATCC 49619

Procedure

1. Prepare a bacterial suspension of the control organism from overnight growth. The suspension should be equivalent to a 0.5 McFarland turbidity.
2. Use the bacterial suspension to inoculate the agar surface as outlined in disk diffusion procedure.
3. Apply antibiotic disks and place in CO₂ incubator within 15 min.
4. Incubate at 35° C for 20-24 h and then measure zone diameters of each antibiotic.

Expected Results

Clindamycin (CC) 19-25 mm

Erythromycin (E) 25-30 mm

Levofloxacin (LVX) 20-25 mm

Trimethoprim-sulfamethoxazole (SXT) 20-28 mm

Vanomycin (VA) 20-27 mm

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BMHQC

Results: Zone sizes

Entering New Lots

MFG Code: BBL

Mueller Hinton + GMB Agar Medium

Frequency of QC testing

Each new lot

Control organisms

Candida albicans ATCC 90028

Candida parapsilosis ATCC 22019

Procedure

1. Prepare a cell suspension (using BBL Prompt) of each control organism from overnight growth.
2. Use the suspension to inoculate the Mueller Hinton + GMB agar surface as outlined in the disk diffusion procedure.
3. Apply disks (FCA and VOR) and place plate in incubator within 15 min.
4. Incubate in an ambient atmosphere at 35 °C for 20-24 h and then measure zones of inhibition.

Expected Results

Antifungal Agent	Disk Content	<i>C. albicans</i> ATCC 90028	<i>C. parapsilosis</i> ATCC 22019
Fluconazole (FCA)	25 µg	28 – 39	22 – 33
Voriconazole (VOR)	1 µg	31 – 42	28 – 37

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: for weekly drug QC under DISCS
otherwise under UNSCHEDULED when entering QC for media

Item Code: MHGMB (QC for media)

Item Codes: VORKB, FCAKB (QC for drugs)

Results: Zone sizes

Entering New Lots

MFG Code: SHM (for media)

MFG Code: BD (for drugs)

Department of Microbiology
QC Procedures
MUG Disks

Frequency of QC testing

Each new lot or shipment, when received

Control organisms

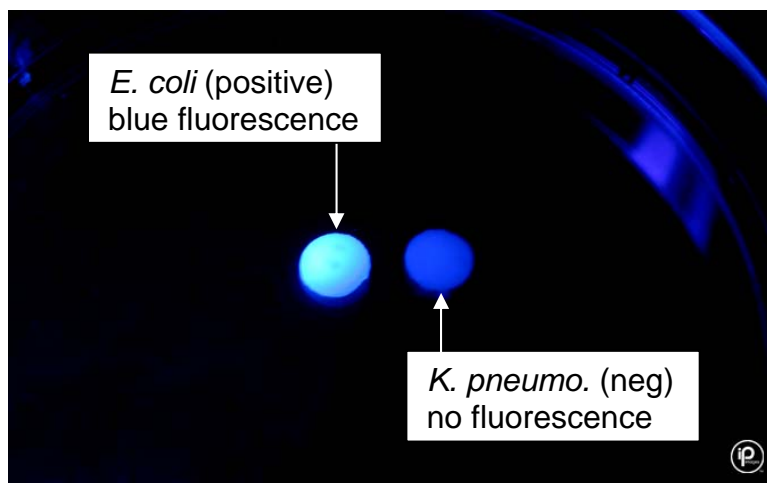
E. coli ATCC 25922

K. pneumoniae ATCC 13882

Procedure

1. Place a MUG disk on the bottom of an empty petri dish.
2. Smear several colonies on the disk.
3. Add one drop of water.
4. Incubate aerobically at $35 \pm 2^\circ\text{C}$ for up to 30 min.
5. Following incubation, examine the disk for fluorescence using a long-wave UV light (360 nm) in a darkened room.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: MUG

Results: POS or NEG

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures
Nitrate Broth Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

E. coli ATCC 25922

Acinetobacter baumannii ATCC 19606

Pseudomonas aeruginosa ATCC 27853

Procedure

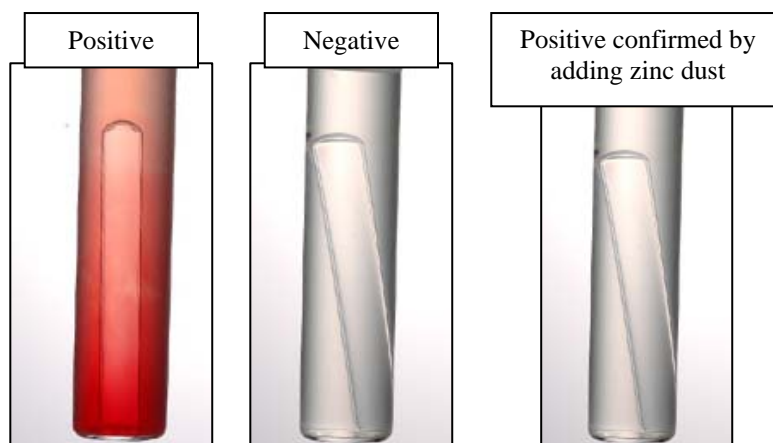
1. Label 3 tubes of Nitrate broth with date and each of the control organism names.
2. Check to be sure there is no gas present in the Durham tube prior to inoculation.
3. Using a sterile inoculating loop, select 2-3 isolated colonies from pure culture and transfer inoculum of each control organism into respective tubes.
4. Replace caps loosely and incubate tubes in an ambient atmosphere at 35 °C for approximately 24 h.
5. After incubation note if gas is present in Durham tubes.
6. Add equal amounts (about 5 drops of each) of Nitrate Reagents A & B.
7. A red color that develops in about 30 s indicates a positive (reduction of nitrate to nitrite).
8. If no red color develops, add a small amount of zinc dust to the tube. Examine tubes for the development of pink or red color within 10 minutes. Tubes that turn pink or red after the addition of zinc dust are confirmed negative. If no color change occurs with the zinc dust the nitrate has been reduced and converted to nitrogen gas.

Expected Results

E. coli ATCC 25922: Positive (red color with addition of Reagents A & B)

Acinetobacter baumannii ATCC 19606: Negative (red color only after zinc dust added)

Pseudomonas aeruginosa ATCC 27853: Positive (no color change after zinc dust is added)



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: NITRBR

Results: OK

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
Nitrate A & B Reagents

Frequency of QC testing

Each new lot or shipment when received

Control organisms

E. coli ATCC 25922

Acinetobacter baumannii ATCC 19606

Pseudomonas aeruginosa ATCC 27853

Procedure

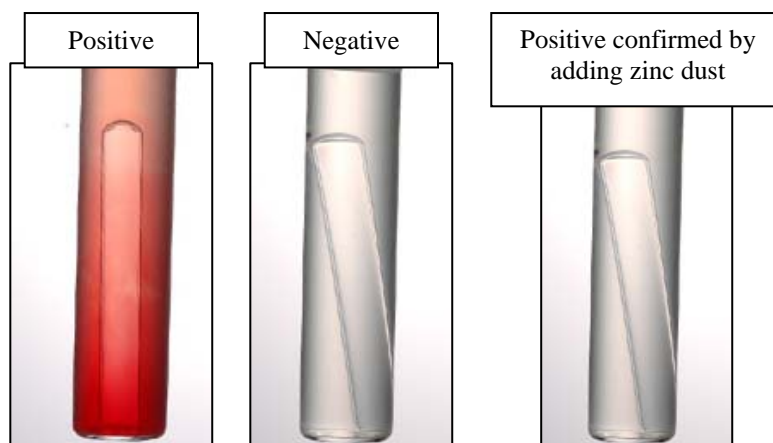
1. Label 3 tubes of Nitrate broth with date and each of the control organism names.
2. Check to be sure there is no gas present in the Durham tube prior to inoculation.
3. Using a sterile inoculating loop, select 2-3 isolated colonies from pure culture and transfer inoculum of each control organism into respective tubes.
4. Replace caps loosely and incubate tubes in an ambient atmosphere at 35 °C for approximately 24 h.
5. After incubation note if gas is present in Durham tubes.
6. Add equal amounts (about 5 drops of each) of Nitrate Reagents A & B.
7. A red color that develops in about 30 s indicates a positive (reduction of nitrate to nitrite).
8. If no red color develops, add a small amount of zinc dust to the tube. Examine tubes for the development of pink or red color within 10 min. Tubes that turn pink or red after the addition of zinc dust are confirmed negative. If no color change occurs with the zinc dust the nitrate has been reduced and converted to nitrogen gas.

Expected Results

E. coli ATCC 25922: Positive (red color with addition of Reagents A & B)

Acinetobacter baumannii ATCC 19606: Negative (red color only after zinc dust added)

Pseudomonas aeruginosa ATCC 27853: Positive (no color change after zinc dust is added)



Computer Entry of Results

Function: MQCE
Select: TESTQC
Category: UNSCHEDULED
Item Codes: NITRAT
Results: OK

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures
OF Media

Frequency of QC testing

Each new lot or shipment, assigned

Control organisms

Klebsiella pneumoniae ATCC 13882

Moraxella catarrhalis ATCC 25238

Pseudomonas aeruginosa ATCC 27853

Procedure

1. Label tubes with date and each of the control organism names.
2. Using a sterile inoculation needle, select 1 isolated colony of control organism for each respective tube.
3. Inoculate each tube by stabbing to within a ¼ inch of the bottom of the tube. Inoculate 2 dextrose tubes and overlay one with 1 mL of mineral oil.
4. Replace the caps loosely and incubate tubes in ambient atmosphere at 35 °C for 24 h.

Expected Results

Tube	Control strain	Expected Results
Base	<i>K. pneumoniae</i> 13882	Green (NEG)
	<i>M. catarrhalis</i> 25238	Green (NEG)
Dextrose w/oil	<i>K. pneumoniae</i> 13882	Yellow (POS)
	<i>P. aeruginosa</i> 27853	Green (NEG)
Dextrose	<i>K. pneumoniae</i> 13882	Yellow (POS)
Lactose	<i>M. catarrhalis</i> 25238	Green (NEG)
Maltose		
Mannitol		
Sucrose		
Xylose		

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: OFBASE, GLU, GLUOIL, L, MALT, MN, SUC, XYL

Results: OK

Entering New Lots

MFG Code: BBL

Department of Microbiology
QC Procedures
Optochin (P) Disks

Frequency of QC testing

Each new lot or shipment when received

Control organisms

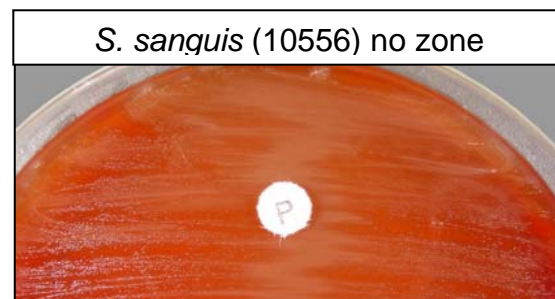
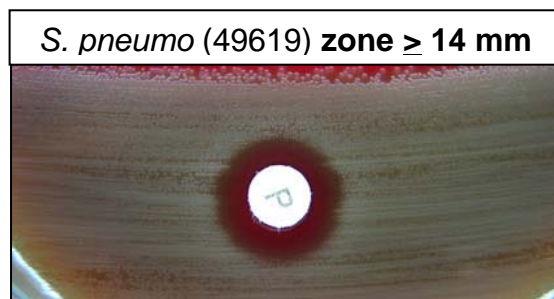
Streptococcus pneumoniae ATCC 49619

Streptococcus sanguis ATCC 10556

Procedure

1. Label 2 blood agar plates and inoculate with respective control organisms by streaking for isolation.
2. Aseptically place an optochin disk on the inoculated agar surface in the primary streak area or at the junction between the primary and secondary streak area.
3. Incubate plates in CO₂ at 35-37 °C for 24 h and then observe for the presence of zones of inhibition.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: TAXOP

Results: POS or NEG

Entering New Lots

MFG Code: BD

Department of Microbiology
QC Procedures
Oxidase Reagent

Frequency of QC testing

Each new lot (made weekly)

Control organisms

Pseudomonas aeruginosa ATCC 27853

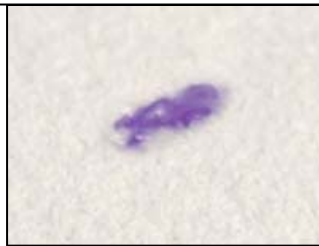
E. coli ATCC 25922

Procedure

1. Saturate a small piece of filter paper with reagent.
2. Using a wooden applicator, select an isolated colony of control organism from BAP and spread inoculum onto saturated filter paper.
3. Repeat testing on other control organism.
4. Observe for development of blue/purple color indicating a positive reaction. No color change indicates a negative reaction.

Expected Results

P. aeruginosa (27853) Positive



E. coli (25922) Negative



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: Weekly under RGNT

Otherwise under UNSCHEDULED

Item Code: OXID

Results: POS or NEG

Entering New Lots

MFG Code: SHM

Department of Microbiology
QC Procedures
Pertussis DFA Stain

Frequency of QC testing

Each time test is performed

Controls

Pertussis Antigen (positive control slide)

E. coli (negative control slide)

Procedure

1. Control slides are prepared in batches and stored at -20°C . See procedure for preparation of control smears. Allow slides to reach RT.
2. FA Conjugate is prepared ahead of time and stored at -20°C . Remove a vial from the freezer and thaw.
3. Apply several drops of conjugate onto the prepared slides and spread over the surface using a wooden applicator.
4. Place slides in moist chamber.
5. Incubate in the dark for 30 min at room temperature.
6. Gently rinse off excess conjugate with distilled water.
7. Air dry.
8. Add 1-2 drops of mounting medium to the slide and apply coverslip.
9. Examine under 100X oil immersion to determine proper staining reactions.

Expected Results

Positive control slide: 3-4+ fluorescence - very small coccobacilli staining bright yellow-green with a clear-cut periphery and non-staining or faint-staining center ("doughnut" appearance).

Negative control slide: no fluorescence

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: PERTST

Results: POS or NEG

Entering New Lots

MFG Code: DIFCO

Department of Microbiology
QC Procedures
Pneumocystis DFA Stain

Frequency of QC testing

Each time test is performed

Control organisms

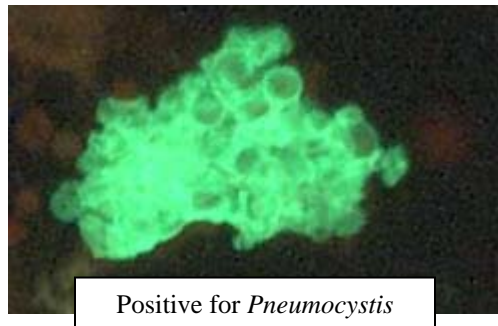
Confirmed previous positive patient

Confirmed previous negative patient

Procedure

1. Control slides are prepared in batches and stored at -20°C . See procedure for preparation of control smears. Allow slides to reach RT.
2. Dispense 1 drop of reagent onto each smear.
3. Place slides in a moist chamber and incubate for 30 min at $35-37^{\circ}\text{C}$. Do not allow reagent to dry.
4. Rinse reagent off slides with a gentle stream of distilled water around the outside of the well.
5. Air dry on $35-40^{\circ}\text{C}$ slide warmer.
6. Add 1-2 drops of mounting medium to the slide and apply coverslip.
7. Scan each smear with 40X. If fluorescent items are observed, use 100X to confirm the cellular morphology consistent with *Pneumocystis*.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: PNEUST

Results: POS or NEG

Entering New Lots

MFG Code: BIORAD

Department of Microbiology
QC Procedures

Pseudomonas P Agar Slant

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Pseudomonas aeruginosa ATCC 27853

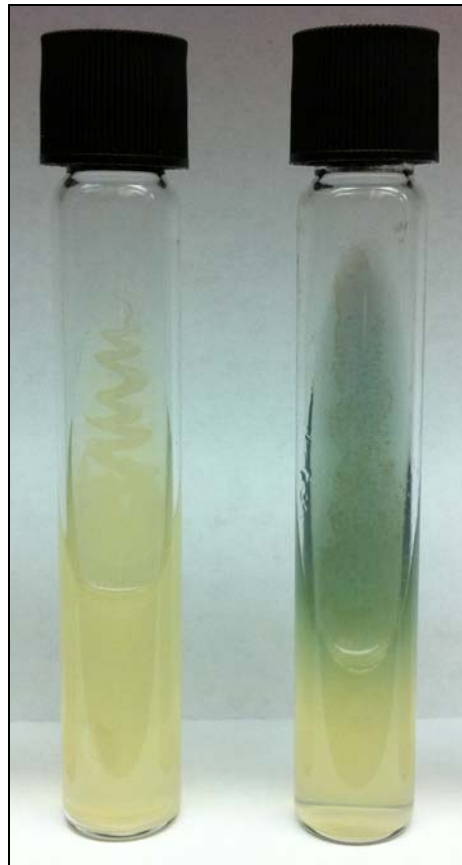
Burkholderia cepacia ATCC 17765

Procedure

1. Select a single, well-isolated colony with an inoculating loop.
2. Streak the surface of the slant (do not stab the agar), and cap loosely.
3. Incubate at $42 \pm 2^\circ\text{C}$ in an aerobic atmosphere.
4. Examine daily for up to 2 days.

Expected Results

***B. cepacia* (17765)**
growth with no pigment



***P. aeruginosa* (27853)**
growth with
blue-green pigment

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: PSP

Results: POS or NEG

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures

PYR (L-pyrrolidonyl- β -naphylamide) Disks

Frequency of QC testing

Each new lot or shipment, when received

Control organisms

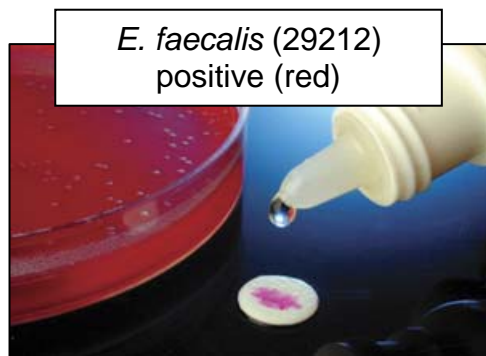
Enterococcus faecalis ATCC 29212

Streptococcus agalactiae ATCC 13813

Procedure

1. Dispense 2 disks onto a glass slide.
2. Moisten each disk with 1 drop of water.
3. Smear 3-5 well-isolated colonies of control organism onto each disk using a wooden applicator.
4. Incubate at room temperature for 2 min.
5. Add one drop of color developer to each disk and examine for immediate pink to red color change within 1 min indicating a pos. reaction.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: PYR

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures

Rapid Trehalose Assimilation Test

Frequency of QC testing

Each new lot or shipment when opened

Control organisms

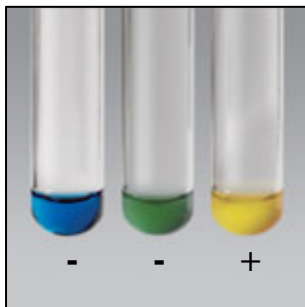
Candida glabrata ATCC 15126

Candida albicans ATCC 90028

Procedure

1. Label 2 Rapid Trehalose Assimilation tubes with control organism names.
2. Using a sterile inoculation loop, select several colonies of the test strain and emulsify in the broth to create a cloudy suspension.
3. Incubate tubes aerobically at 42°C. For best results, cover the opening by placing the cap on the tube without tightening.
4. Monitor tubes for up to three hours for a color change to yellow.

Expected Results



C. glabrata 15126 = Positive

C. albicans 90028 = Negative

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: TREHAS

Results: POS or NEG

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures

Regan-Lowe Agar Medium

Frequency of QC testing

Each new lot or shipment when received

Control organisms

Bordetella pertussis ATCC 9340

Staphylococcus aureus ATCC 25923

E. coli ATCC 25922

Procedure

1. Working in the biological safety cabinet (for *B. pertussis*), make a basic cell suspensions for each test strain directly from growth on weekly sub plates and adjust the turbidity to a 0.5 McFarland standard.
2. Dilute the suspensions 1:10 in normal saline.
3. Using a 10 µL loop (large urine loop), inoculate the agar and streak for isolation.
4. Mark the *B. pertussis* Culture Log with QC final in 3 days.
5. Incubate media in ambient atmosphere at 35 °C for 72 h. Colonies of *B. pertussis* should appear as small, domed, glistening, and white to gray. *S. aureus* and *E. coli* strains should inhibited in size and/or recovery.

Expected Results

Bordetella pertussis growth on RL agar



S. aureus and *E. coli* should be inhibited

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: RL

Results: POS or NEG

Entering New Lots

MFG Code: BBL

Sodium Deoxycholate (Bile Solubility Test)

Frequency of QC testing

Each new lot

Control organisms

Streptococcus pneumoniae ATCC 49619

Enterococcus faecalis ATCC 29212

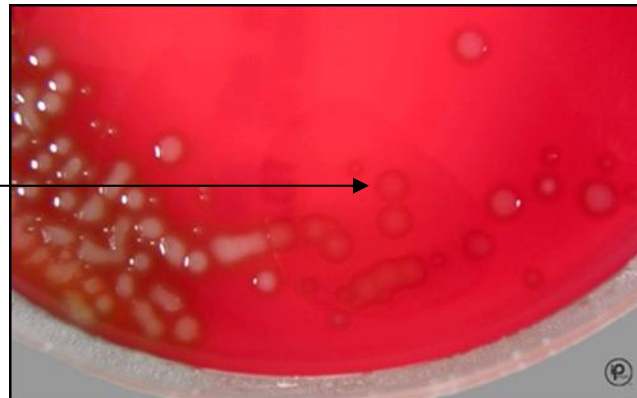
Procedure

1. Using a transfer pipette, dispense one drop of reagent directly on a well-isolated colony of control organism (18-24 h growth on BAP).
2. Do not invert the plate. Incubate the agar plate at 35 °C for 30 min.

Expected Results

E. faecalis (29212) = Negative (colony remains intact and visible)

S. pneumoniae (49619)
Positive
(colony disintegrates)



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: BILE

Results: POS or NEG

Entering New Lots

MFG Code: SHM

Department of Microbiology
QC Procedures
Spore Stain

Frequency of QC testing

Each time test is performed

Control organisms

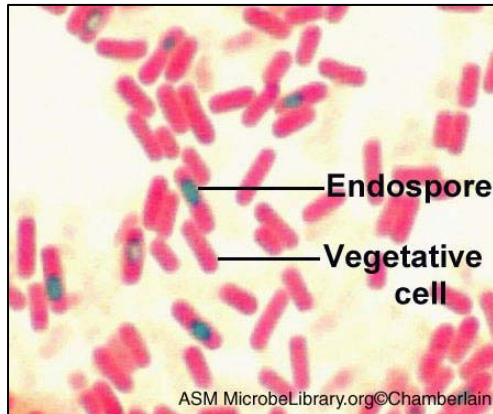
Positive control slide: *Bacillus* species

Negative control slide: *E. coli* ATCC 25922

Procedure

1. Flood each smear with Malachite green and stain for 10 min.
2. Rinse slides over sink with tap water.
3. Counterstain with safranin for 30 s.
4. Rinse with tap water. Blot edges of slides to remove excess water and allow smears to dry.
5. Examine smears under oil immersion (100X) for the presence of spores.

Expected Results



Spores should stain green on the *Bacillus* species slide.
Vegetative *Bacillus* cells and *E. coli* cells do not retain malachite green and counterstain pink from the safranin.

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: SPRSTN

Results: POS or NEG

Entering New Lots

MFG Code: SHM

Department of Microbiology
QC Procedures
StaphTEX Blue Reagent

Frequency of QC testing

Each lot or shipment received.

Controls

StaphTEX™ Blue Positive & Negative Control Reagents

Staphylococcus aureus ATCC 25923 & *Staphylococcus epidermidis* ATCC 12228

QC Procedure with Control Reagents

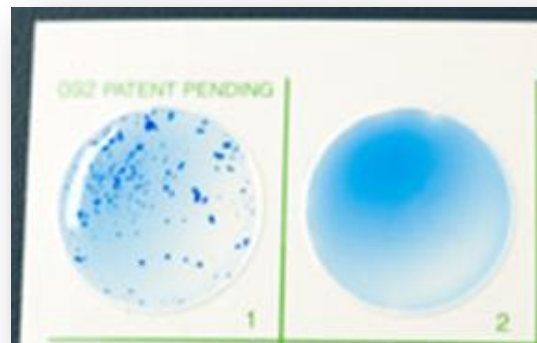
1. Place a drop of resuspended Latex Reagent in two separate reaction circles on the card.
2. Place a drop of the resuspended Positive Control and Negative Control Reagents in separate reaction circles on the reaction card.
3. Use a wooden applicator stick to thoroughly mix the reagents by lightly rubbing the surface of the reaction card inside limits of the reaction circle.
4. Gently hand-rock the reaction card for 20 s.
5. Examine mixture for agglutination. Do not use a magnifying lens.
6. The Positive Control Reagent must provide obvious agglutination, while the Negative Control Reagent must not produce agglutination within the 20 s.

QC Procedure with Control Organisms

1. Use fresh 18-24 h old cultures of the control organisms. If necessary, prepare subcultures and test the new lot/shipment on the following day.
2. Test the control organisms as outlined above in the test Procedure.
3. *Staphylococcus aureus* ATCC 25923 must provide obvious agglutination, while *Staphylococcus epidermidis* ATCC 12228 must not produce agglutination within the 20 s.

Expected Results

Positive Control
Reagent and
S. aureus (25923)
(clumps within 20s)



Negative Control
Reagent and
S. epiderm. (12228)
(suspends uniformly)

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: STPHBL

Results: POS or NEG

Entering New Lots

MFG Code: HARDY

Department of Microbiology
QC Procedures

Strep A Antigen (Acceava®) Kit

Frequency of QC Testing

External controls are run with each new lot or shipment when received and every 30 d, while in use. Perform QC with each new untrained operator. Internal controls must be read and documented for each test.

Controls

The same lot of external controls should be used for each new kit for lot to lot comparison. External controls are prepared separately using *S. pyogenes* ATCC 19615 and *S. agalactiae* ATCC 13813 as outlined in the test procedure.

Procedure

External Quality Control

1. Retrieve one positive and one negative control from the -70°C freezer and allow materials to thaw at room temperature.
2. Proceed with testing by following the test procedure.

Internal Quality Control

1. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

Expected Results



Positive



Negative

Documenting QC

Record the internal control on the test log
Record external QC in LIS

Computer Entry of Results

Function: MQCE
Select: TESTQC
Category: UNSCHEDULED
Item Code: ACCSTA
Results: POS and NEG

Entering New Lots

MFG Code: INV

Department of Microbiology
QC Procedures
Streptex Reagents

Frequency of QC Testing

Each new lot or shipment of latex reagents (when received) or enzyme (when opened)

Control Organisms

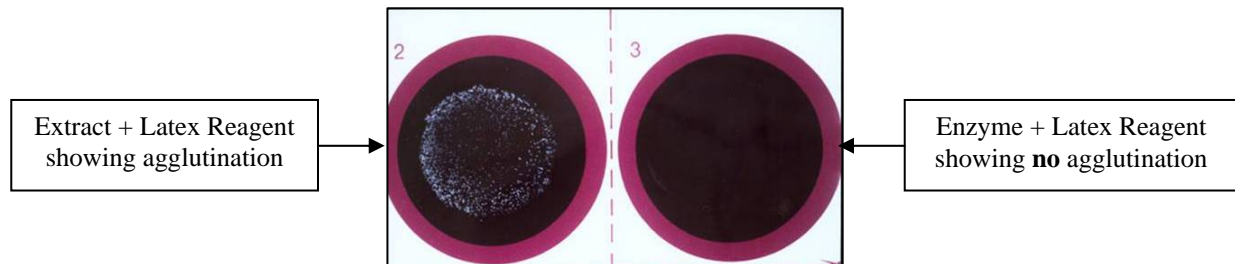
Streptococcus pyogenes ATCC 19615 (for Latex Reagent A)

Streptococcus agalactiae ATCC 13813 (for Latex Reagent B)

Procedure

1. Following the Streptex procedure, prepare enzyme extract. If you are testing the Latex A Reagent you will need *S. pyogenes* 19615. If you are testing the Latex B Reagent you will need *S. agalactiae* 13813. If you are testing the enzyme you will need to prepare separate extracts from both control organisms.
2. After the extraction process is complete, place 1 drop of extract on a test circle on a reaction card.
3. Place a drop of enzyme without any added organism into a separate test circle.
4. Shake bottle of latex reagent to resuspend particles.
5. Place 1 drop of latex reagent into the extract and 1 drop into the enzyme.
6. Mix the contents of each circle with a wooden stick.
7. Rock the card gently for up to 1 min while watching for agglutination.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: STRXA (Latex A), STRXB (Latex B), STRXEN (Enzyme)

Results: POS or NEG

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures
Superoxyl Test

Frequency of QC testing

Each new lot or shipment and with each new user.

Control organisms

Neisseria gonorrhoeae ATCC 43069

Neisseria lactamica ATCC 23970

Streptococcus pyogenes ATCC 19615

Procedure

1. Under a biosafety cabinet, using a wooden applicator, touch the center of an 18 to 24 h, well-isolated colony to a clean glass slide. Be sure the material is visible to the naked eye on the slide.
2. Place one drop of 30% peroxide reagent on the slide and observe immediately for effervescence.

Caution! 30% H₂O₂ is extremely caustic to skin. Gloves should be worn when performing this test. If skin contact occurs flush immediately with water for at least 15 min. See [Hydrogen peroxide 30% MSDS](#) for additional first aid information.

Expected Results

- Positive: *N. gonorrhoeae* 43069 shows the immediate formation of brisk bubbling.
- Weak: *N. lactamica* 23970 shows a delayed, slow bubbling.
- Negative: *S. pyogenes* 19615 shows no bubbles or a few bubbles after 20 s.



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Codes: SOXQC

Results: POS, WEAK, NEG

Entering New Lots

MFG Code: FSHR

Department of Microbiology
QC Procedures

Trichrome Stain for Parasites

Frequency of QC testing

Weekly and with each new lot

Controls

Positive control slide: positive patient
(Typically a sample with *Giardia*)

Procedure

1. Prepare and stain control smear in the same manner as patient samples (see procedure manual).
2. Examine preparation under 100X for organism morphology and staining characteristics.
3. The cytoplasm of cysts and trophozoites should appear blue-green, tinged with purple. The nuclear chromatin typically stains red to purplish-red.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: Weekly under STAINS

Otherwise under UNSCHEDULED

Item Code: TRCHST

Results: POS

Entering New Lots

MFG Code: HRLC

Department of Microbiology
QC Procedures
Vancomycin Disk for ID

Frequency of QC testing

Tested weekly and each new lot

Control organisms

Enterococcus faecalis ATCC 29212

E. coli ATCC 25922

Procedure

1. Using pure cultures of control organisms create suspensions equivalent to a 0.5 McFarland using a BBL Prompt.
2. Using a sterile swab, inoculate separate BAPs with each control organism. Streak the entire plate in 3 directions to achieve a confluent lawn of growth.
3. Using sterile forceps, place a 30- μ g Vanco disk in the center of each plate.
4. Incubate plates in CO₂ at 35 °C for 18-24 h.
5. Observe the plates for the presence of zones of inhibition around the Vanco disks

Expected Results

E. faecalis (29212) zone \geq 12 mm

E. coli (25922) zone \leq 9 mm

Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: for weekly QC under DISCS
otherwise under UNSCHEDULED

Item Code: VAID

Results: Zone sizes

Entering New Lots

MFG Code: BD

Department of Microbiology
QC Procedures

Wellcolex for Salmonella or Shigella Kit

Frequency of QC Testing

Each new kit opened

Control s

Kit controls

Salmonella – Red, Blue, and Green

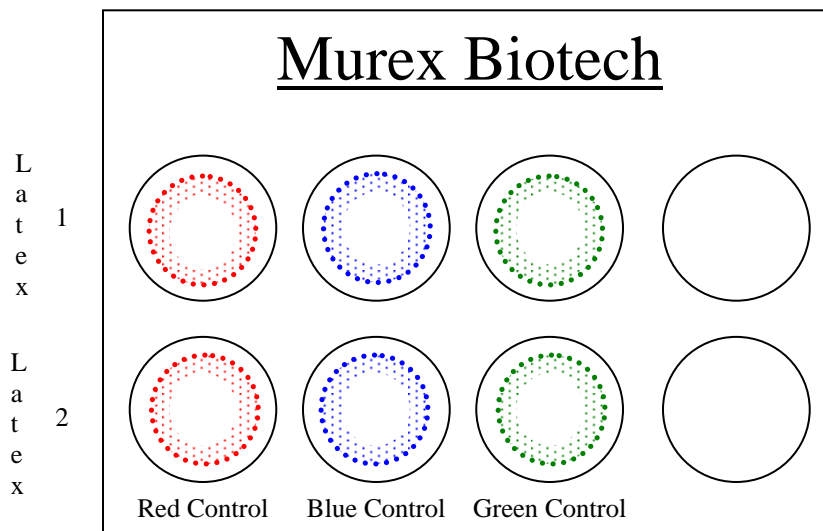
Shigella – Red and Blue

Procedure

1. Bring reagents to room temperature prior to use.
2. Shake vials vigorously to resuspend particles.
3. Test each of the positive control reagents against both latex reagents. Follow the Wellcolex test procedure by using the positive controls in place of the bacterial suspension.

Expected Results

Observe for agglutination of colored latex particles corresponding to positive controls used.



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: WXSALM and WXSHIG

Results: BLUE (B key), GREEN (G key), and RED (R key)

Entering New Lots

MFG Code: REMEL

Department of Microbiology
QC Procedures
X & V Disks

Frequency of QC testing

Each new lot or shipment, when received

Control organisms

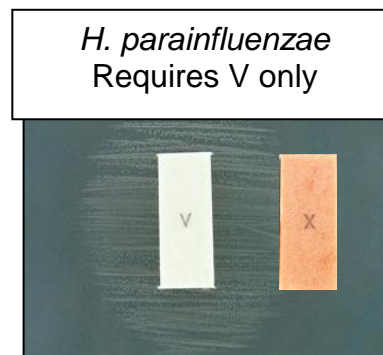
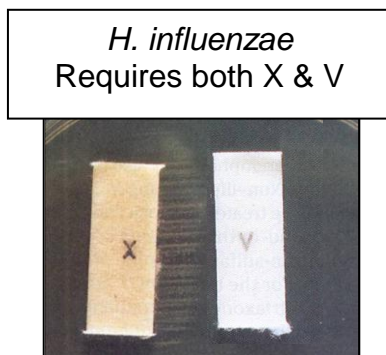
Haemophilus influenzae either ATCC 49247 or 35056

Haemophilus parainfluenzae ATCC 7901

Procedure

1. Prepare bacterial suspensions for each control organism using a BBL Prompt to achieve turbidity equivalent to 0.5 McFarland.
2. Using a sterile swab, inoculate a lawn onto the surface of 2 separate BHI agar plates.
3. Place X & V strips on the agar surface about 1 cm apart.
4. Incubate in CO₂ at 35 °C for 18-24 h.

Expected Results



Computer Entry of Results

Function: MQCE

Select: TESTQC

Category: UNSCHEDULED

Item Code: XV

Results: OK

Entering New Lots

MFG Code: BD

Document Control History

Microbiology Director Approval: Dr. Ann Robinson 05/02/2008

Microbiology Supervisor Reviews: Jerry Claridge 05/02/2008, 01/06/2010, 03/2011, 03/2013, Jason Ammons 6/2015

Revisions & Updates:

01/12/2011 Updated Fecal Fat and Mueller Hinton Agar. Added Blood MH Agar, HTM, and MUG Disk. 03/05/2011 Added Bird Seed Agar, Caffeic Acid Disk, CGB Agar, CHROMagar MRSA II, and Superoxyl Test. 03/08/2012 Changed 10B to 10B Arginine. Modified Campy CVA – dilute suspension 1:100. Added CHROMagar Salmonella. 05/07/2012 Added BHI & BHI with 6.5% Salt. 06/27/2013 Changed BD GenOhm Cdiff, GBS, and MRSA assays to BD MAX assays. 03/17/2014 Updated Coagulase Plasma for new reagent from Hardy and combined slide and tube procedures to the same page. Added FilmArray RP and BCID. 07/30/2014 Added, “Use the lot number on the bottle not on the box” to the Streptex guide. 10/10/2014 Updated Cryptococcus Antigen QC for lateral flow assay. 12/18/14 Added QC reference for Enteric Bacterial PCR Panel BD MAX Assay, added, reference for rapid ESBL for blood cultures, updated HIV for new kit, updated MRSA for new XT kit. Deleted Rapid RSV and Influenza. 2/19/2015 Added MacConkey Sorbitol Agar. 6/17/15 Removed gelatin, lead acetate, and penicillin disk for ID.