CHRISTUS SPOHN Health System

Policy / Procedure Title: Microbiology Quality Assurance

SOP Number:	M.1.40	**Effective Date:**	04/07/11
Department:	Microbiology	**Revision Date:**	09/12/2016
Policy (P), Procedure (PR)or Both (P/P):	P/P	**Version:**	02

Applicable Standards	
Standard	Organization
CAP	MIC.10070
CAP	MIC.11015
CAP	MIC.11017
CAP	MIC.11020
Related Documents	

Version History		
Version	Effective Date	Retired Date
1	04/05/11	02/19/15
2	04/16/15	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By/Initials & Date
04/07/11	01	Medical Director	J. Lewis
01/18/13	01	Biennial Review	K. Porche
04/16/15	02	Minor Revision	J. Lewis
09/12/16	02	Biennial Review/Minor Revision	K. Porche

Distribution
CSHCC Memorial Microbiology SOP Volume I
CSHCC Shoreline Microbiology SOP Volume I
CSHCC South Microbiology

I. Quality Control Review

The Microbiology Quality Control Program is under active review. The Microbiology Lead Tech (Technical Supervisor) as technical director designee reviews all QC from all shifts with documentation on a monthly basis (SSH and SMH only).

a. Control specimens are tested in the same manner and by the same personnel as patient samples.
b. Results of patient testing are not released unless the Quality Control is found to be within target limits or until proper investigation has been made.
c. QC Corrective Action forms are filled out by the tech noting the discrepancy when Quality Control values fall outside acceptable ranges. All follow-up is documented and signed/reviewed by the Technical Supervisor.
d. Patient test results obtained in an analytically unacceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient results.

II. Quality Control – General design

Quality Control design encompasses all phases of testing from Pre-Analytical to Analytical to Post Analytical. QC plans for non-CLIA waived assays have specific individualized quality control plans based on historical risk assessment for each facility. **Refer to IQCP Binder for plan details.**

A. Specimen Processing
   1. All specimens must be accompanied by an adequate requisition including:
      a. Full name of patient.
      b. Hospital number (if outpatient – date of birth)
      c. Source of specimen
      d. Time and date of collection
      e. Test to be done
      f. Time and date of receipt by laboratory. (Recorded in computer when verified.)
   2. If a specimen is unlabeled or does not meet the criteria for testing (see S.O.P. **Specimen Rejection Criteria**)
      a. Notify nursing unit or submitting facility.
      b. Cancel computer orders with reason for canceling and person notified.

B. Reagents
   1. Reagents made in laboratory - prepare a label with the following information:
      a. Chemical name, use and storage requirements
      b. Concentration (include formula or "recipe")
      c. Date made and initials of person making reagent
      d. Expiration date – if applicable
   2. Dispose of all out-of-date reagents by flushing into drain followed by water.
   3. Whenever reagents require water, use only deionized water taps which are Type I water.
   4. Commercially prepared reagents will be labeled according to the following standard:
      a. Date received
      b. Date opened – if opening container changes expiration date

c. Date of expiration – all reagents are stored according to manufacturer's recommendations and used within their indicated expiration dates.

5. Reagent Quality Control testing are recorded on the appropriate recording form.
6. New reagent lots are checked against suitable reference material, which may include ATCC strains of common organisms, organisms with known identifications that are not necessarily ATCC strains or patient samples if appropriate to the specific test or reagent kit. If appropriate, new reagent lots are checked against old reagent lots.
7. Reagents in kits having multiple components are not used across lot numbers unless specified by the manufacturer that it is acceptable to do so.
8. All test procedures performed in the microbiology laboratory have control materials available either commercially, in reagent kits, or acquired from patient samples.

C. Glassware and Pipettes
   1. Routine glassware will be washed in bio-degradable detergent, rinsed in tap water, rinsed in deionized water twice and dried in oven. (Applies only to CSH-Memorial)
   2. Only sterile disposable pipettes are used for bacteriologic purposes. They are disposed of in biohazard containers.

D. Control Organisms
   1. Where required, ATCC Quality Control strains are maintained and used for primary quality control. (Detailed instructions are found with each procedure.) Stocks are obtained via commercially purchased loops/gels or lyophilized organisms.
   2. Certain fastidious organisms used for quality control are maintained on enriched media. Subcultures of control organisms are checked for purity by colonial morphology. In event of a test failure, results are recorded, and corrective action is begun with documentation on the QC Corrective Action Form.

III. Quality Control – Frequency of testing

A. Each time of use (positive and negative controls) – each batch or run – and with each new lot/shipment
   1. Auramine Rhodamine Fluorescent Stain for AFB (SMH)
   2. Chlamydia/GC (SMH) – also includes internal controls with each test

B. Each day of use (positive and negative controls) and with each new lot/shipment
   1. Acid Fast Stain – Kinyoun method – (SSH, SMH)
   2. Modified Acid Fast Stain (SSH, SMH)
   3. Occult blood / Gastrocult (SSH, SMH, SSO)

C. Each week of use (positive and negative controls) and with each new lot/shipment
   1. Gram stain (SSH, SMH, SSO)

D. Each Lot Number and Shipment (positive and negative controls)
   1. Catalase (SSH, SMH)

2. Staph latex (SSH, SMH)
3. Beta Lactamase-Cefinase (SSH, SMH)
4. Oxidase (SSH, SMH)
5. C. albicans Rapid Testing (Murex) (SSH, SMH)
6. Lactophenol cotton Blue (intended reactivity) (SSH, SMH)
7. Indole Spot (SSH, SMH)
8. M-cat butyrate (SSH, SMH)
9. PYR (SSH, SMH)
10. PathoDX Strep Agglutination (SSH, SMH)
11. Haemophilus Quad (SSH, SMH)
12. Optochin (SSH, SMH, SSO)
13. Bacitracin (SSH, SMH, SSO)
14. Pneumoslide (SSH, SMH)
15. APNA (SSH, SMH)
16. Urea Disk (SSH, SMH)
17. Hippurate (SSH, SMH)
18. Ninhydrin (SSH, SMH)

E. **Once per Lot Number and Shipment –** Refer to IQCP
   1. Rapid Anaerobe ID (SSH, SMH) – per manufacturer guidelines
   2. Vitek2 Aerobic ID (GN, GP) (SSH, SMH) – per manufacturer guidelines
   3. API 20E (SMH) – per manufacturer guidelines
   4. API Coryne (SMH) – per manufacturer guidelines
   5. Rapid NH-Plus (SMH) – per manufacturer guidelines
   6. Yeast ID (SSH, SMH) – per manufacturer guidelines

F. **External controls per lot/shipment and not to exceed 31 days. Internal controls are performed with each test cartridge and are documented within LIS.** Refer to IQCP for non-CLIA waived rapid antigen tests for more details.
   1. Strep A direct (SSH, SMH, SSO)
   2. Influenza A/B (SSH, SMH, SSO) – CLIA waived
   3. Legionella NOW (SSH)
   4. Pneumo NOW (SSH)
   5. Crypto Antigen Direct (SSH,SMH)
   6. Giardia Antigen Direct (SSH,SMH)
   7. EZ Leuko Vue (SSH,SMH)
   8. Immunocard STAT EHEC (SSH, SMH)
   9. Rotavirus (SSO)
   10. RSV Ag (SSO)

G. **External controls per lot/shipment and not to exceed 31 days. Internal controls are performed with each test cartridge.** Refer to appropriate IQCP for more details.
   1. Great Basin Scientific Cdiff (SSH only)
   2. Nanosphere Verigene BC-GP & BC-GN

IV. Quality Control – Antimicrobial Susceptibility Testing

A. Weekly Susceptibility Quality Control – Vitek 2 MIC cards (SSH, SMH)
   See SOP for individual card requirements and control limits. Weekly QC after completion of 15-20 day QC. Each lot or new shipment of panels is also submitted to QC before being placed in use. Refer to appropriate IQCP for more details.

B. Weekly Susceptibility Quality Control - Kirby Bauer Disk Susceptibility (SMH only)
Weekly QC after completion of 15- 20 day QC. Each lot or new shipment of disks is also submitted to QC before being placed in use. Refer to appropriate IQCP for more details.

C. E-Test (SMH only)
CLSI defined QC for appropriate bug/drug combination. Daily QC required - only performed when patient testing is done unless 15-20 QC is established which thus allows weekly QC. Refer to appropriate IQCP for more details.

V. Quality Control - Media

A. Media Quality Control
1. No media is prepared in-house.
2. Expired, unsuitable, or contaminated media is discarded and replaced with fresh media.
3. Prepared, purchased media is controlled as set out in guidelines of the CLSI Document M-22-A3, 2004. All media will be examined visually for breakage, contamination, hemolysis, appearance, and evidence of freezing or overheating. The date received, Lot #, and expiration date are recorded in the Media Q.C. Manual.
4. All media should be in visibly satisfactory condition i.e. plates smooth, adequately hydrated, uncontaminated, appropriate color and thickness. Tubed media should not be dried or loose from sides of the tube.
5. Those media having a high failure rate and which were previously defined by CLSI as "non-exempt" are tested for ability to support growth and growth characteristics by the user, as applicable.
6. Those media failing quality control testing will be removed from service and recorded on the QC Corrective Action form as well as reported to the manufacturer for documentation and credit.
7. All media previously defined as "Exempt" from User QC will be logged as manufacturer tested (Refer to BBL Media Preparation Manuals for documentation of Q.C. done) and checked for appearance. Refer to Media IQCP Plan for more details.

VI. Quality Control – Temperature and Instrument Checks

A. Temperatures of all incubators, heat blocks, refrigerators, and ambient room are recorded daily.
B. Countertops will be cleaned with disinfectant before beginning work and at frequent intervals throughout the day. Countertop disinfection is recorded once daily.
C. Atmosphere
1. Gauges on CO_2 incubators are checked daily by digital readout. The digital readout is verified monthly against Fyrite. Concentration is maintained between 5% and 10%.
2. Anaerobe systems are checked and documented on each day of use for adequate anaerobic conditions as appropriate for each system (anaerobic chamber, anaerobic jar, anaerobic bags).
3. Microaerophilic conditions are maintained by the use of the EZ Gas Pak Campy System. Campylobacter QC organism is subbed every 3 days to keep organism alive for media QC needs and other applicable QC and so as to monitor acceptability of the EZ Pak system.
D. Maintenance - Effort is made to adhere to maintenance schedules set up by Maintenance and BioMed.

1. Biological Safety Cabinets are certified once per year by commercial company.
2. Non-calibrated thermometers are checked before being placed into service with an NBS Certified thermometer. NIST thermometers or instrument integrated thermometers are used where possible.
3. Microscopes are cleaned and adjusted once per year by Biomedical Engineering.
4. Pipettes are calibrated twice a year by Biomedical Engineering.
5. Instrument function checks are maintained for each instrument as suggested by the manufacturer.
6. Instrument manuals are available for troubleshooting instrument failures either within the departments or from Biomedical Engineering. Maintenance records are also available.

VII. Quality Control – Serological

No antisera/serological reagents are used in this laboratory. All serological tests are referred to Texas Department of Safety and Health Services (TDH).

VIII. Quality Control - Stains

1. Stains of proven quality are used.
2. Slides of good quality are used. Slides are alcohol flamed before use.
3. ATCC strains of gram positive and gram negative organisms are used to evaluate gram stain performance. Quality control is performed with each new lot# and shipment of reagent and weekly thereafter.

IX. Instrument Comparability

When more than one non-waived instrument is used to test for a given analyte, the instruments are checked against each other at least twice a year for comparability.

- Vitek2 (SSH only) – each ID and AST card duplicated on both instruments
  - ID – via lot/shipment streamlined QC – run QC material simultaneously on both instruments
  - AST – via weekly QC material which is rotated across analyzers weekly
- Sofia Flu (All facilities) – via Lot/Shipment External QC swabs – read across all analyzers every 31 days
- Great Basin (SSH only) – via previously characterized samples – perform same sample across all analyzers
- Verigene SP Processors (SSH and SST) – via External QC material – performed across each analyzer

➢ For qualitative results the same result must be obtained (i.e., species level identification, positive/negative, detected/not detected).
➢ For AST results, Same MIC interpretation (S,I,R) for all antibiotics.

X. Quality Control – Reporting Results

Results of tests involving the above are recorded in the appropriate Quality Control Book. Control specimens are tested in the same manner as patient samples and by the same personnel as patient samples. In the event of test failure, all components are examined and corrective action instituted, usually by substitution of fresh components for all testing. Definitive dependence upon such controls is withheld pending correction of problem. Patient results are not reported until discrepancy in Quality Control is verified. Corrective Action Form is filled out with each occurrence and signed by the Lead Technologist/Technical Supervisor.