IQCP for Commercially Prepared "CLSI-Exempt" Media

PURPOSE

Commercially prepared CLSI-Exempt microbiological used in this laboratory include:

- 5% Blood Trypticase Soy Agar (TSA)
- MacConkey agar
- Columbia (CNA) agar
- TSA/MacConkey biplate
- Thioglycolate broth (used for primary specimen only)

Commercially prepared blood culture bottles include:

- Blood bottles with Trypticase Soy Broth

TEST SYSTEM PRIMARY SOP'S INCLUDE:

- Media Sterility and Acceptability Check

HISTORICAL QUALITY REVIEW

Previously CLIA inspector guidelines recognized use of NCCLS (CLSI) standard M22 (proposed standard first published in 1985; most recent version is M22-A3, 2004) which indicates that user retesting of commercially prepared microbiological culture media with quality control strains is unnecessary for those media that are of proven acceptability. M22 lists media that fall into this category and labels them as "exempt". For these media, the user need only examine them for obvious defects including:

change in expected color of media	cracked or damaged plates
agar detached from the plates	excessive bubbles or rough surfaces
frozen or melted agar	excessive moisture or dehydration
unequal filling of plates	obvious contamination*
insufficient agar in the plates (<3 mm)	presence of precipitates
hemolysis of blood containing media	

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HISTORICAL QUALITY REVIEW, CONTINUED

*examine 2 plates/tubes of a specific medium from each batch/lot/shipment upon receipt and examine all plates/tubes immediately before inoculation with patient specimens

This laboratory has been following CLSI M22 since 2008 without any significant "exempt media" QC problems.

Processes to mitigate patient reporting errors based on use of unacceptable exempt media are addressed in this IQCP.

REGULATORY AND ACCREDITATION REQUIREMENTS:

A. Checklist from Accrediting Agency:
   - CAP MICROBIOLOGY
B. Method verification:
   - Documentation of initial checks of the media used in this laboratory is filed in the Bacteriology Department.
C. Training of personnel:
   - Completion of training documented in department employee files.
D. Competency Assessment:
   - Competency assessment records filed in department employee files.

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QUALITY CONTROL PLAN

A. Before, or concurrent with the initial use:

- Check each batch of media for sterility if sterility is required for testing;
- Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and
- Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

B. Follow the manufacturer's specifications for using media and supplies and be responsible for results.

C. Manufacturer:

- Package inserts indicate that QC testing of exempt media includes use of QC strains and procedures recommended in CLSI M22 and do not indicate that the user must perform further testing with QC strains.
- "Certificates of Quality" (CoQ) and "Certificates of Compliance (CoC)" are provided by the manufacturer with each lot/shipment of exempt media which indicate the specific lot of media has met performance specifications described in CLSI M22.
- Manufacturer informs users of any problems with exempt media that are identified subsequent to release of the media with "product alerts".
- Manufacturer has hotline available for reporting problems with defective media.

-Instruction on how to obtain package inserts, CoQs, CoCs, and product alerts are located Media QC Binder. –

D. Reference used during collection of information:

- [1]NCCLS (CLSI): *Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – third edition.* NCCLS document M22-A3. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA. 2004.
- FAQ for IQCP, revised April 2015, Question 42 – states in part: "*For example, laboratory documentation showing visual quality checks of media are acceptable in-house data. The laboratory may also include manufacturer's quality certificates as part of the information considered in its risk assessment.*" Reference: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/FAQs-IQCP.pdf

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QUALITY CONTROL PLAN, CONTINUED

Final QCP

A. Based on our Risk Assessment and Quality Assessment, the QCP for "exempt media" consists of following the instructions that are provided in explicit detail in P&P Media Sterility and Acceptability Check.

B. Review of manufacturer's CoAs and COCs provided with each batch/lot/shipment of media upon receipt of shipment.

C. Visual inspection of representative units of "exempt media" for any physical defects or contamination upon receipt.

D. Visual inspection of all units of "exempt media" for any physical defects or contamination immediately before inoculation with primary specimen or cultivated microorganism.

E. Maintenance of logs to record media received, any defects observed and any interactions with manufacturer about defective media. Also record any instances where defective media was used for patient's specimens and any resultant reporting errors. Supervisor will review these logs monthly for any trends warranting attention.

F. Inform manufacturer of any defective media beyond random occurrences.

G. Continual monitoring of storage environment for media

H. Review of manufacturer's product inserts and media alerts as received.

I. During initial training and competency assessment, instruct all staff about:
   - media storage conditions
   - The need for them to continually look for any defects, contamination or inconsistencies in growth on "exempt media" and inform supervisor of such occurrences immediately.

J. Whenever a problem or potential problem is identified with "exempt media", inform staff about the problem.

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QUALITY ASSESSMENT

A. Summary of in-house data for quality control of exempt CLSI-media. Exempt media were inspected upon receipt according to P&P Media Sterility and Acceptability Check.

B. Review of QC records, incidence reports and staff feedback obtained over the past 12 months of exempt media demonstrated no occurrence of defective media (physically damaged primarily due to cracked petri plates) and no occurrence of contaminated media. Records documenting media receipt, inspection and defects are located in the Media QC Binder.

Quality Assessment: Ongoing Monitoring for QCP Effectiveness (Performed by supervisor and/or section head)

A. Reasons for QC failures will be examined and addressed as needed in a new/updated risk assessment: 1) Has a new risk factor been identified? 2) Does this change the frequency of risk? 3) Does the risk factor change the potential severity of harm to patient?

B. Exempt media: MAC, CNA, TSA, Thio – certificates can be obtained from manufacturer's web site.

C. Chocolate Agar Plate: Not exempt - send to Regional Lab for QC.

D. Blood culture bottles: manufacturer Certificate of Compliance comes with shipment.

E. Review of manufacturer's product inserts, CoAs, CoCs, and media alerts as received and revise QCP as needed.

F. Annual review of media sterility and acceptability protocol and revise as needed.

G. Monthly review of all equipment maintenance/monitoring logs according to standard laboratory protocols. Take corrective action and revise QCP as needed.

H. Regular training and competency assessment according to standard laboratory protocols. Modify training and revise QCP as needed.

I. Continual participation in this institution's quality program that addresses specimen handling and erroneous specimen labeling. Take corrective action and revise QCP as needed.

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RISK ASSESSMENT Review of QC records, incidence reports, and staff feedback obtained over the past 12 months of exempt media demonstrated no occurrence of defective media (physically damaged primarily due to cracked petri plates) and no occurrence of contaminated media. Risk assessment based on the records obtained over the past 12 months is acceptable with no occurrences of patient harm.

Risk Assessment and Determination of Risk Level

Frequency of occurrence:	**Severity of harm to patient:**
Unlikely (once every 2-3 years)	Negligible (temporary discomfort)
Occasional (once per year)	Minor (temporary injury; not requiring medical intervention)
Probable (once per month)	Serious (impairment requiring medical intervention)
Frequent (once a week)	Critical (life threatening consequences)

Risk Level:
Risk level for any Risk Factor that is "Not Acceptable" must be addressed in the IQCP.
Risk level for any Risk Factor that is "Acceptable" may be included in the IQCP at the discretion of the Laboratory Director.

Risk Acceptability Matrix

Probability of Harm	Negligible	Minor	Serious	Critical
Frequent	Not Acceptable	Not Acceptable	Not Acceptable	Not Acceptable
Probable	Acceptable	Not Acceptable	Not Acceptable	Not Acceptable
Occasional	Acceptable	Acceptable	Acceptable	Not Acceptable
Unlikely	Acceptable	Acceptable	Acceptable	Acceptable

Risk Acceptability Assignment

Risk Factor (Possible Sources of Error)	**Frequency of occurrence**	**Severity of harm to patient**	**Risk Level**
Preanalytical			
Specimen (Primary):			
Patient identification	probable	minor	Not Acceptable
Collection/container/volume	frequent	negligible	Not Acceptable
Integrity	frequent	negligible	Not Acceptable
Transport	frequent	negligible	Not Acceptable

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Storage	probable	negligible	Acceptable
Specimen (Organism):			
Colony age/viability/sampling	unlikely	minor	Acceptable
Media type	unlikely	minor	Acceptable
Pure isolate	unlikely	minor	Acceptable
Analytical			
Testing Personnel:			
Training	probable	negligible	Acceptable
Competency	occasional	negligible	Acceptable
Experience	occasional	negligible	Acceptable
Proficiency Testing	occasional	negligible	Acceptable
Staffing	occasional	negligible	Acceptable
Reagents:			
Shipping/receiving/storage	probable	minor	Acceptable
Expiration dates	probable	minor	Acceptable
Batch sterility	probable	minor	Acceptable
Visual inspections	frequent	negligible	Acceptable
Environment:			
Temperature/airflow/humidity/ ventilation	occasional	negligible	Acceptable
Utilities	occasional	negligible	Acceptable
Test System (Media):			
Contamination	probable	minor	Acceptable
Organism growth	occasional	minor	Acceptable
Postanalytical			
Test Results:			
Organism growth correlations	occasional	serious	Acceptable
Review reported results	unlikely	minor	Not Acceptable
Clinician feedback	unlikely	critical	Not Acceptable

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Risk Assessment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factor	**Possible Error**	
Preanalytical		
1A: Specimen - Biological	• Improper specimen procurement/ handling/processing	• Adhere to Specimen Collection P&P that addresses patient identification and specimen collection, labeling, transport, storage and remedial actions to control improperly handled specimens or delayed specimens. During initial training and competency assessment, emphasize: • Proper specimen handling/processing is the most critical part of any test • Each unit of media must be inspected for contamination and any physical defects prior to use for inoculation of primary specimens • Failure to inoculate/streak correctly (no isolated colonies) and delayed incubation may result in delayed microbiology reports
Patient/specimen identification		See above (Specimen)
Collection/container/ volume		See above (Specimen)
Integrity		See above (Specimen)
Transport		See above (Specimen)
Storage		See above (Specimen)
1B: Specimen - Organism		
Colony age/viability/ sampling	• Organism non-viable	During initial training and competency assessment, emphasize: • Lengths of time various organisms generally remain viable in various specimens/media
Media type	• Media appropriate for the organism is used • Media fails to support growth of test organism • Media is contaminated	During initial training and competency assessment, emphasize: • Appropriate media/incubation conditions for various organisms • Recognition of contaminated media

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Pure isolate	• Mixed inoculum	During initial training and competency assessment, emphasize: • Selection of pure cultures for subculture • Potential sources of contamination during testing process
Analytical		
2: Testing Personnel	• Incompletely trained • Unaware of updated protocols	During initial training and competency assessment, emphasize: • Key aspects of media use and assessment of media quality including those described in this IQCP
Training		See above (Testing Personnel)
Competency		See above (Testing Personnel)
Experience		See above (Testing Personnel)
3: Reagents (Media)		During initial training and competency assessment, emphasize standard rules to always: • Take responsibility for using media appropriately (all staff) • Maintain media at proper storage conditions • Check expiration dates • Incubate and check representative sample of media for sterility • Inspect each unit of media for physical defects and random contamination prior to use as described in this IQCP
Receiving/storage	• Incorrect ordering • Damaged packaging	• Designated staff member(s) assigned to inventory (order/receipt) media to ensure media supply is properly maintained and media are handled appropriately on receipt
Expiration dates		See above (Reagents)
Visual Inspection		See above (Reagents)
4: Environment		During initial training and competency assessment, emphasize standard rules for: • Take responsibility for any possible instrument/ environmental problem (out of the ordinary observation) (all staff) • Equipment maintenance • Temperature recording (done automatically with continuous monitoring device) • Electrical supply

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Temperature/airflow/ humidity/ ventilation		See above (Environment)
Utilities		See above (Environment)
5: Test System		During initial training and competency assessment, emphasize standard rules for: • Take responsibility for any out of the ordinary observation with any media • Inspecting each unit of media for contamination and any physical defects prior to use
Contamination	• Random contamination on individual unit of media not recognized	During initial training and competency assessment, emphasize standard rules for: • Inspecting each unit of media for contamination prior to use
Organism growth	• Media "unexpectedly" fails to support the growth of a microorganism	• Review manufacturer's CoA to ensure QC was successful as described in CLSI M22 • Check for inconsistencies in organism growth on all media types • Check for inconsistencies in organism growth vs Gram stain
Postanalytical		
6: Test Results		• Supervisor maintains records of reporting errors and corrected reports; corrective action to address any potential "exempt media" issues
Clinician feedback	• Complaints/suggestions regarding potential erroneous results due to "exempt media" quality	See above (Test Results) • Incorporate suggestions into QA plan, as appropriate.

Controlled Documents

The following controlled documents support this procedure.

Reference
CAP MIC.21240
CAP COM.50300
CAP COM.50200

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HISTORY PAGE

Type of Change: New Major, Minor	Description of Change(s)	Name of Responsible Person/Date	Operations Director, Area Laboratory	CLIA Laboratory Director Review/Date	Date Change Implemented
New		Judith Remolar 5/31/16			
Minor	Regional Template revision	Ruby Co 6/18/18			
Major	Added detailed information for Risk Assessment	Ruby Co 10/16/18	Mary Lou Beaumont 10/19/18	Joe Co 10/19/18	10-19-18