Please note that some references to protocol, publications, performance data etc. are fictitious in this EXAMPLE. Please use your own DATA for your IQCP.

The following represents one example of how you might organize your IQCP for commercially prepared CLSI-exempt media. Please note:

1) *This example is based on CLSI-exempt media that might be used in one laboratory.*
2) *Depending on requirements of a particular accreditation organization, the format and content of this example may or may not be acceptable for an IQCP.*
3) *A practical strategy would be to review this example together with materials provided by your media manufacturer, your accreditation organization, and CMS when developing your IQCP for CLSI-exempt media.*

IQCP for Commercially Prepared "CLSI-Exempt" Media

Facility:
Regional Medical Center

Test System:
Commercially prepared CLSI-Exempt microbiological media from XYZ Media Company used in this laboratory include:

- Blood agar
- MacConkey agar
- Columbia (CNA) agar
- Cefsulodin irgasan novobiocin (CIN) agar
- Brucella agar w/hemin/Vitamin K
- Middlebrook agar
- Lowenstein-Jensen agar
- Inhibitory Mold Agar (IMA)
- Sabouraud's dextrose agar
- *LIM broth
- *Selenite broth
- *Thioglycolate broth
- **Triple Sugar Iron agar (TSI)
- **Urease agar

Commercially prepared blood culture bottles from XYZ include:

- Blood bottles with trypticase soy broth

*used for primary specimens only
**used for cultivated organisms only
Remaining media used for culturing primary specimens and cultivated organisms

Test System Primary SOPs include:
#2.1.1 "Processing Microbiological Specimens" (includes selection of media for plating specimens)
#7.1.8 "Blood Culturing Using XYZ System"
#10.2.2 "Quality Control of Media and Reagents"

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	

*examine 10 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 for over 25 years without any significant "exempt media" QC problems. Any problem related to media performance has involved:

1) random and infrequent physical defect (listed above) in a single unit of media
2) random and infrequent contamination of a single unit of media

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

Information Used to Conduct Risk Assessment

Regulatory and Accreditation Requirements:
Checklist from Accrediting Agency: Checklist items a, b, c
Method verification: Media from MicroLab Media Company has been used in this laboratory since____. Documentation of initial checks of this media for acceptable quality are filed in_____.
Training of personnel: Completion of training documented in_____.
Competency Assessment: Competency assessment records filed in_____.
Proficiency Testing: Rotate personnel; all personnel review results. Proficiency testing records filed in_____.
Quality Control: CLIA '88 specifies: (4) Before, or concurrent with the initial use— (i) Check each batch of **media** for sterility if sterility is required for testing; (ii) 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 (iii) Document the physical characteristics of the **media** when compromised and report any deterioration in the media to the manufacturer. (5) Follow the manufacturer's specifications for using reagents, **media**, and supplies and be responsible for results. Alternatively, an IQCP can be developed to modify the quality control procedures for "exempt media". **CMS recognition of this option documented here:** 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*

Test System Information:

Manufacturer:

- Package inserts indicate that QC testing of exempt media includes use of QC strains and procedures recommended in CLSI M22 and does not indicate that the user must perform further testing with QC strains.
- "Certificates of Quality" (CoQ) are provided 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.

Package inserts, CoQs and product alerts are located _____.

Reference used during collection of information for RA:

[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.

Summary of in-house data for quality control of exempt CLSI-media:

Exempt media were inspected upon receipt according to SOP _____.

Additional media quality checks include the following as specified in SOP_____:

- Examine each unit of media for physical defects or contamination as described in the list above under "Historical Quality Review" immediately before inoculation with patient specimens or organisms.
- Examine each unit of media that has been inoculated/incubated for possible contamination or other defect by observing for: 1) growth outside the primary streak (plated media); 2) growth on only one unit of media inconsistent with growth on other units when multiple units are inoculated with the same specimen; 3) unexplainable results (e.g., fungus growing on the same lot of blood agar plates from several patient's CSF specimens).

Review of QC records, incidence reports and staff feedback obtained over the past 12 months which involved approximately 150 shipments and 200,000 units of exempt media demonstrated:

- less than 0.01% occurrence of defective media (physically damaged primarily due to cracked petri plates)
- less than 0.01% occurrence of contaminated media.

Occurrences of physically defective media were random and not lot specific. Physically defective media were not used for testing patient specimens; they were discarded.

Five separate blood agar plates from the same lot/shipment grew *Penicillium* spp. The manufacturer was notified and the remaining units in the lot were discarded.

Other occurrences of contamination were random and not lot specific.

No patient reports were affected due to any physically defective or contaminated media.

Records documenting media receipt, inspection and defects are located_____.

Note that the cutoff for an acceptable failure rate detailed in CLSI M22-A3 is 0.5%. This means 5 out of 1000 units of a specific CLSI-exempt medium may demonstrate a random defect.

Summary of corrected reports and physician complaints:

There were no incidents of corrected reports or physician complaints as a result of defective exempt media.

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.

Note: Patient response plays a significant role in addition to AST results in guiding antimicrobial therapy and provides a limited safeguard for preventing harm in patients for which erroneous AST results are reported or results are delayed.

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
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

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 procedures in SOP #2.1.1 that addresses patient identification and specimen collection, labeling, transport, storage and remedial actions to control improperly handled specimens or delayed specimens. • Annually review representative specimen processing errors (N=10 to 15) with all staff involved with patient 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	During initial training and competency assessment, emphasize: • Appropriate media/incubation conditions for various organisms • Recognition of contaminated media

	• Media is contaminated	
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)
Proficiency Testing		• All appropriate staff read (and sign off) on PT sample critiques • Supervisor share any pertinent information from PT surveys with other staff, as appropriate
Staffing	Inadequate to perform testing without errors	• Supervisor to annually review appropriate staffing to support appropriate evaluation of media upon receipt and prior to use
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
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
Review reported results		See above (Test Results)

Clinician feedback	• Complaints/suggestions regarding potential erroneous results due to "exempt media" quality	See above (Test Results) • Incorporate suggestions into QA plan, as appropriate.

Final QCP for AST System XYZ
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 SOP #10.2.2 "Quality Control of Media and Reagents".
Review of manufacturer's CoAs provided with each batch/lot/shipment of media upon receipt of shipment.
Visual inspection of representative units of "exempt media" for any physical defects or contamination upon receipt.
Visual inspection of all units of "exempt media" for any physical defects or contamination immediately before inoculation with primary specimen or cultivated microorganism.
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 to review these logs monthly for any trends warranting attention.
Inform manufacturer of any defective media beyond random occurrences.
Continual monitoring of storage environment for media
Review of manufacturer's PIs and media alerts as received.
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.
Whenever a problem or potential problem is identified with "exempt media", inform staff about the problem.

Quality Assessment: Ongoing Monitoring for QCP Effectiveness (Performed by supervisor and/or section head)
Reasons for QC failures, PT failures, and patient isolate reporting errors 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?
Daily review of patient results for reporting errors and clinician complaints. Take corrective action and revise QCP as needed.
Review of manufacturer's PIs, CoAs and media alerts as received and revise QCP as needed.
Annual review of "Quality Control of Media and Reagents" protocol and revise as needed.
Regular review of Proficiency Testing results after each report is received from sponsor of PT program. Take corrective action and revise QCP if necessary when PT results are not acceptable.

Monthly review of all equipment maintenance/monitoring logs according to standard laboratory protocols. Take corrective action and revise QCP as needed.		
Regular training and competency assessment according to standard laboratory protocols. Modify training and revise QCP as needed.		
Continual participation in this institution's quality program that addresses specimen handling and erroneous specimen labeling. Take corrective action and revise QCP as needed.		
This QCP has been reviewed and is approved by the laboratory director (as named on the CLIA license).	**Signature**	**Date**