9 -IQCP EXEMPT MEDIA

EXAMPLE

IQCP EXEMPT MEDIA

Written Summary Author(s):	Signature	Date

RA Participants - Printed Name	Signature	Date

Risk Assessment Summary

Specimen **Time Period of Review:** **January 1, 2014** **to** **October 31, 2015**

I. The following policies/procedures were reviewed:

A. Identification of Patient, #1836

B. Labelling of Specimens, #1837

C. Occurrence Management - Quality Improvement, #4438

D. Microbiology Quality Control Program - Illinois, #4611

II. Review of QIVs for this period was conducted. No QIVs related to exempt media (as defined in CLSI M22) were noted.

Test System **Time Period of Review:** **January 1, 2014** **to** **October 31, 2015**

I. The following policies/procedures were reviewed:

A. Media for Mycobacteriology Set Up, #6054

B. Fungus Media Set-Up Chart, #4780

C. Central Lab Media Selection Chart (Rosemont), #4754

II. Listing of CLSI (M22) exempt media used at central lab - Remel, bioMerieux and BD products:

A. Bacteriology exempt culture media:

* Blood agar
* MacConkey agar
* CNA agar
* Hektoen agar
* bioMerieux blood culture media - aerobe and anaerobe bottles

B. Mycology exempt media

* Inhibitory mould agar
* Brain heart infusion agar with 5% blood, CG (Chloramphenicol and Gentamicin)

C. Mycobacteriology exempt media

* BD MGIT media (Middlebrook 7H9 Broth)
* Lowenstein-Jensen Slant

Reagents **Time Period of Review:** **January 1, 2014** **to** **October 31, 2015**

I. The following policy/procedures were reviewed:

A. Microbiology Quality Control Program - Illinois, #4611

II. All media were used within expiration dates, and stored at temperatures indicated per manufacturer (Remel and BD)

III. Review of vendor recalls, none noted for exempt media identified in this IQCP, these are located in a binder on shelf outside of day shift supervisor's office.

IV. Vendor packing slips and 'Certificates of Quality' for each lot number and shipment certify that specific lot numbers of exempt media have met all performance and QC criteria for the product that are equal to or exceed specifications defined in CLSI M22 document, and were reviewed for timeframe indicated. When evaluating commercially prepared CLSI-exempt media, a visual inspection is also performed with each lot number and shipment and documented on the packing slip looking for:

A. No cracked or damaged plates
B. No frozen or melted agar
C. No obvious contamination
D. No unequal filling of the plates
E. No hemolysis of blood media
F. No agar detached from petri plates
G. No excessive moisture/dehydration/precipitates
H. No change in expected color of the media
I. No excessive bubbles or rough surface

This documentation is located on ACL "W" drive, ICL Micro QC_PT Results, choose year 2014 or 2015, ICL-Microbiology QC Records, Media-Reagent, Remel QC Certification

V. Additionally, media is visually checked for contamination immediately before inoculation with specimens, and when reading cultures, media is visually examined for organisms growing on a piece of media and not on others, or growing inbetween streaking marks.

VI. Review of the timeframe indicated, one lot on 7/23/14 lot #526424 of MacConkey plated media was observed to have contamination on both the surface of the media and throughout the media. Vendor Remel was notified and all 8 cases of that lot were replaced. Approximately 2 cases of 100 plates were already in use, and another 6 cases were unopened in the refrigerator. Examination of the plates in use do not indicate any patient impact.

Environment **Time Period of Review:** **January 1, 2014** **October 31, 2015**

I. The following policy/procedures were reviewed:

A. Temperature-CO2-Humidity Recording and Maintenance of Temperature Dependent Equipment, #4430
B. Sensoscientific Wireless Environmental Monitoring System, #1802
C. Environment of Care Management Plan, #965

II. Review of temperature/humidity room temperature records for this time period was conducted, no issues noted. These records are located on the "W" Drive in folder name "ICL Micro QC_PT results", then choose a folder of the year for review, then choose folder ICL-Microbiology QC records, then folder Temperature CO2, then Microbiology

Specimen Risk Assessment: Exempt Media (as defined by CLSI M22)

Source of error or failure	Probability	Consequences	Total	*Risk Level	Measures to Control Risk	Relevant SOP #
	(1 rare, 2 remote, 3 occasional, 4 probable, 5 frequent)	(1 insignificant, 2 minor, 3 serious, 4 critical, 5 catastrophic)	(Probability X Consequences = Total)			
Patient identification	1	2	2	Low	Two patient identifiers required	Identification of Patients, #1836
Patient preparation	NA	NA	NA	NA	NA	NA
Specimen collection	1	2	2	Low	External Directory of Service (DOS) contains detailed information on specimen collection.	ACL DOS online information
Specimen labeling	1	3	3	Low	Two patient identifiers required. Labeling errors are monitored with the QIVs	Labeling of Specimens, #1837. Occurrence Management - Quality Improvement, # 4438 Rejected/Discrepant Specimen, #1846
Specimen storage, preservation, stability	1	3	3	Low	Specimen storeage and transport requirements are in the Directory of Services	ACL DOS online information
Specimen transport	1	3	3	Low	Specimen storeage and transport requirements are in the Directory of Services	ACL DOS online information Specimen Transport Containers, #3749 ACL Transport Logs, #3749
Specimen processing	1	3	3	Low	Media requirements for each specimen type for processing and plating	Inoculation of Routine Microbiology Specimens, #4597

Specimen rejection	1	3	3	Low	Specimens are assessed for acceptability and are rejected as needed. Specimen rejection monitored. Ordering physician/site is notified of the rejection	ACL DOS online information
Specimen referral	NA	NA	NA	NA	NA	NA

Risk Levels

1 to 5 = **Low**

6 to 9 = **Moderate**

10 to 12 = **High**

≥12 = **Extreme**

NOTE: Components identified at a *Risk level of **Moderate, High or Extreme** must be addressed in the Quality Control Plan to identify how that risk will be mitigated. Any item for the component identified as Low risk level may be included in the Quality Control Plan at the discretion of the site Laboratory Director.

Test System Risk Assessment: Exempt Media (as defined by CLSI M22)

Source of error or failure	Probability	Consequences	Total	*Risk Level	Measures to Control Risk	Relevant SOP #
	(1 rare, 2 remote, 3 occasional, 4 probable, 5 frequent)	(1 insignificant, 2 minor, 3 serious, 4 critical, 5 catastrophic)	(Probability X Consequences = Total)			
Inadequate sampling	1	2	2	Low	Procedures address low volume sampling	Inoculation of Routine Microbiology Specimens, #4597
Contamination	1	3	3	Low	Training and procedures are provided to check for contamination prior to plating patient specimens. Visual quality checks are documented upon receipt of media.	Inoculation of Routine Microbiology Specimens, #4597
Organism growth	1	3	3	Low	Training and procedures are provided to check for inconsistencies in organisms growth on all media types. Discrepant cultures are reviewed	Inoculation of Routine Microbiology Specimens, #4597
Result reporting	1	2	2	Low	Result entry is manual, and results are reviewed	Review of Culture Results, #4681

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Extreme

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Testing Personnel Risk Assessment: Exempt Media (as defined by CLSI M22)

Source of error or failure	Probability	Consequences	Total	*Risk Level	Measures to Control Risk	Relevant SOP #
	(1 rare, 2 remote, 3 occasional, 4 probable, 5 frequent)	(1 insignificant, 2 minor, 3 serious, 4 critical, 5 catastrophic)	(Probability X Consequences = Total)			
Training	1	3	3	Low	All associates are trained prior to performing testing, all documentation complete for associates performing this assay	Training and Competency Assessment for Laboratory Personnel, #1671
Competency testing	1	3	3	Low	All associates are competency tests prior to performing testing, new associates after six months of hire, and annually thereafter.	Training and Competency Assessment for Laboratory Personnel, #1671
Proficiency testing	1	3	3	Low	Proficiency Testing is treated and performed same as patient samples, no proficiency testing failures, all results acceptable.	Proficiency Testing Procedure, #4427
Staffing	1	3	3	Low	Staffing is monitored with Labor Forecast	NA

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Competency testing	1	3	3	Low	All associates are competency tests prior to performing testing, new associates after six months of hire, and annually thereafter.	Training and Competency Assessment for Laboratory Personnel, #1671
Proficiency testing	1	3	3	Low	Proficiency Testing is treated and performed same as patient samples, no proficiency testing failures, all results acceptable.	Proficiency Testing Procedure, #4427
Staffing	1	3	3	Low	Staffing is monitored with Labor Forecast	NA

Risk Levels

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Environment Risk Assessment: Exempt Media (as defined by CLSI M22)

Source of error or failure	Probability	Consequences	Total	*Risk Level	Measures to Control Risk	Relevant SOP #
	(1 rare, 2 remote, 3 occasional, 4 probable, 5 frequent)	(1 insignificant, 2 minor, 3 serious, 4 critical, 5 catastrophic)	(Probability X Consequences = Total)			
Temperature	1	2	2	Low	Room temperature, refrigerator and incubator temperatures are continually monitored electronically and manually	Sensoscientific Wireless Environmental Monitoring System, #1802 Temperatture-CO2-Humidity Recording and Maintenance of Temperature Dependent Equipment, #4430
Airflow/ventilation	1	2	2	Low	HVAC system monitored	Environment of Care Management Plan, #965
Light intensity	1	2	2	Low	Adequate laboratory lighting	Environment of Care Management Plan, #965
Utilities	1	2	2	Low	Adequate laboratory utilities	Environment of Care Management Plan, #965
Adequate space	1	2	2	Low	Space is not compromised	Environment of Care Management Plan, #965

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Exempt Media (as defined by CLSI M22)

Reagent Risk Assessment:

Source of error or failure	Probability	Consequences	Total	*Risk Level	Measures to Control Risk	Relevant SOP #
	(1 rare, 2 remote, 3 occasional, 4 probable, 5 frequent)	(1 insignificant, 2 minor, 3 serious, 4 critical, 5 catastrophic)	(Probability X Consequences = Total)			
Shipping/receiving	1	2	2	Low	Media is shipped and received per manufacturer recommendations	Microbiology Quality Control Program - Illinois, #4611
Storage condition requirements	1	2	2	Low	Package insert of kit is followed	Microbiology Quality Control Program - Illinois, #4611
Expiration date	1	2	2	Low	Media is used within expiration dates	Microbiology Quality Control Program - Illinois, #4611

Risk Levels

1 to 5 = Low

6 to 9 = Moderate

10 to 12 = High

≥12 = Extreme

NOTE: Components identified at a *Risk level of **Moderate, High or Extreme** must be addressed in the Quality Control Plan to identify how that risk will be mitigated. Any item for the component identified as Low risk level may be included in the Quality Control Plan at the discretion of the site Laboratory Director.

Test/Test System: EXEMPT MEDIA (as defined in CLSI document M22)

Manufacturer's QC instructions Exist (Y/N): NO

If yes, describe instructions:

Component	Source of error	QC activity	Number	Type	Frequency (ex. Daily, monthly, periodic)	Acceptability Criteria

*Upon receipt of exempt media visual inspection will be performed as outlined in Microbiology Quality Control Program, # 4611. Failed media will be brought to the supervisor's or tech specialist attention and addressed immediately.

*Media will be checked for contamination immediately before inoculation with patient specimens. Contaminated media will be brought to the attendtion of the supervisor or tech specialist and addressed immediately.

* Suspected media contamination when reviewing cultures will be brought to the attention of the supervisor or tech specialist and addressed immediately.

*Vendor QC alerts and bulletins will be reviewed and acted on appropriately as necessary.

* QC Acceptability Criteria is defined in Microbiology Quality Control Program, # 4611

IQCP Approval/Authorization

ACL Site:		**CLIA License #:**	
Address:			
City/State:			

I approve that the test/assay listed below may be performed using the defined Individualized Quality Control Plan based on the Risk Assessment, Quality Control Plan, and Quality Assessment information and documentation that was provided and reviewed.

Test Name:	Exempt Media (as defined by CLSI document M22)
Manufacturer:	Remel, BD, bioMerieux
Site Laboratory Director:	
Signature:	
Date:	
Implementation Date:	

IQCP – QUALITY ASSESSMENT

Assessment activity - description
Physician Feedback - *Continually monitored through CCT
Increase in QC failures - *Continually monitored by monthly QC review
Unexplained errors - * Continually monitored by QIV daily/monthly QIV review
Increase in instrument errors/messages - * Continually monitored
Specimen - *Continually monitored by rejected specimens
Environment - *Continually monitored continually by SensoTech
Testing Personnel - *Continually monitored by competency testing and training of new associates
Reagents - *Continually monitoring of expiration dates
Test Systems - *Continually monitoring of visual media checks
Review of PT results - *Continually monitored by active review of PT results
Review of competency records - *Continually monitored
Specimen rejection logs -
Method comparison/Cal. verification data
Evaluation of corrective actions implemented