EXAMPLE # 1

IQCP for Exempt Media

Test System: Exempt Media as defined by CLSI document M22

Facility:

Written by:

Date:

Implementation Date: _____

This risk assessment and IQCP plan has been approved by:

_____

on _____

EXAMPLE # 1

1. **Historical Quality Review**

The following is a list of the CLSI-exempt Remel media used in our laboratory:

- Blood agar (TSA with Sheep Blood)
- Columbia CNA agar with 5% Sheep Blood
- MacConkey agar
- Todd Hewitt CNA (LIM broth) agar
- PEA agar with sheep blood
- XLD agar
- Bacteroides fragilis/ LKV Blood agar Biplate
- Anaerobic Blood agar (CDC formulation)
- Sabaroud Dextrose agar pH 5.6
- Mycobiotic agar
- Lowenstein Jensen agar

- Commercially prepared CLSI-exempt media undergoes a visual inspection upon receipt for:
  - Intact agar
  - Frozen or melted media
  - Unequal filling
  - Insufficient agar
  - Appropriate color
  - Smooth surface
  - Properly hydrated
  - Presence of precipitation
  - Sterility

- Media is also checked for contamination before inoculating patient specimens and before sub-culturing organisms

Information Used to Conduct Risk Assessment

1. Specimen
   a. The following policies/procedures were reviewed:
      - Patient/ Specimen Identification Policy (section 2.9)
      - Specimen Identification and General Acceptability Criteria (section 2.12)
      - Quality Control Protocol & Acceptability Criteria (section 2.2)
      - Collection and Care of Microbiology Specimens (section 2.121)
2. Test System
   a. The following procedures were reviewed:
      - Suggested Culture Media (section 3.4)
      - Culture Media for Anaerobes (section 4.20)
      - Processing and culturing Mycology Specimens (section 14.3)

b. Quality control data for new lot/shipment of Media was reviewed for 18 months (January 2014 to June 2015)

EXAMPLE # 1

3. Test Personnel
    a. The following policies/procedures were reviewed:
        - Competency Assessment for Laboratory Testing Personnel (section 2.20). Competency Assessment (CA) is performed 6 months after initial training and annually thereafter Documentation filed in Manager's office.
        - Microbiology CAP Specimen Handling (section 2.1)

4. Environment
    a. Policy for temperature Monitoring (section 2.13)

5. Reagents
    a. Quality Control Protocol and Acceptability Criteria (section 2.2)
    b. Remel's Certificate of Quality states that specific lot numbers have met "Quality Assurance for Commercially prepared Microbiological Culture Media". This document is found in every media shipment

Risk Assessment Summary

1. In the time frame mentioned (January 2014 to June 2015) there were no unacceptable parameters noted in the media QC log sheets for any of the media received
2. All media were used by the expiration dates and stored at temperatures indicated per manufacturer

EXAMPLE # 1

Risk Assessment

Determination of Risk Level Scale

Probability of Harm	**Severity of Harm**			
	No risk	**Low** (not requiring medical intervention)	**High** (impairment requiring medical intervention)	**Critical** (permanent impairment requiring medical intervention)
Frequent (1/wk)	Acceptable	Not acceptable	Not acceptable	Not acceptable
Probable (1/mo)	Acceptable	Acceptable	Not acceptable	Not acceptable
Occasional (1/ 6-12 mo)	Acceptable	Acceptable	Acceptable	Not acceptable
Unlikely (once every 2/3 yrs)	Acceptable	Acceptable	Acceptable	Acceptable

EXAMPLE # 1

Risk Assessment- Measures to Control Risks

Risk Factor	Possible Error	How can sources of error be reduced?	Risk Level with solutions in place
Specimen			
Patient identification Collection/container/volume Transport Specimen Integrity Storage	Improper specimen procurement/handling/processing	Adhere to procedures 2.9, 2.12, 2.2, 2.121 addressing patient identification specimen collection by source, labeling, transport, storage Competency assessment performed	Acceptable. Specimens rejected if mislabeled or improperly handled
Testing Personnel			
Training/Competency	Improper training can lead to inappropriate media setup technique and inaccurate results or delays in reporting results	During initial training and competency testing, emphasize the key aspects of media usage	Acceptable – training is completed and competency is checked prior to tech performing and reporting patient results.
Proficiency Testing	Reporting incorrect results on CAP surveys	See above	Acceptable– Review of CAP survey results shows no errors in testing for the past year.
Staffing	Staff shortages can cause errors if appropriate care isn't taken to check media before use	Supervisor/ designee to review appropriate staffing needs daily	Acceptable. Measures in place to avoid staffing issues
Reagents:			
Shipping receiving/storage	Media not shipped/stored per manufacturer's instructions	Reagents are shipped and stored according to manufacturer's instructions	Acceptable. Products not properly shipped/ stored are discarded
Expiration Dates	Media used past expiration date	Educate personnel to check dates before use	See above
Environment:			
Temperature/airflow/humidity/ ventilation	Inadequate storage and/ or incubator temperatures may cause erroneous results	Daily monitoring of refrigerators, incubators. Policy for temperature Monitoring (section 2.13) During initial training and	Acceptable. Measures in place to detect environmental factors

EXAMPLE # 1

		competency assessment, emphasize importance of equipment maintenance, and notification of environmental problems to supervisor/manager	
Test System:			
Contamination	Contaminated media used to setup patient specimens	Training and yearly competency testing. Quality Control Protocol and Acceptability Criteria 2.2	Acceptable. Techs trained to check for contamination before setting up cultures
Organism growth	Known organism not growing as expected	Training and yearly competency testing to detect inconsistencies	Acceptable. Techs trained to know expected organism characteristics
Test Results:			
Review results	New lot/shipment QC not recorded	Monthly review of QC records by supervisor/lead tech	Acceptable. Measures in place to review QC monthly

EXAMPLE # 1

Quality Control Plan (QCP) for Exempt Media

1. Upon receipt of media, visual inspection will be performed as outlined in CLSI-M22. Media not meeting all criteria will be brought to the attention of the manager or lead technologist to be addressed immediately
2. Media will be checked for contamination before inoculation with patient specimens. Contamination will be brought to the attention of the manager or lead technologist to be addressed immediately
3. Suspected media contamination when reading cultures will be brought to the attention of the manager or lead technologist to be addressed immediately
4. Remel QC alerts and bulletins will be reviewed and acted on appropriately as necessary
5. Competency assessment as it pertains to Media Quality Control is performed annually

Quality Assessment: Ongoing Monitoring for QCP Effectiveness

1. Monthly review of Media QC new shipment/lot logs by supervisor/lead tech
2. Monthly review of equipment monitoring logs
3. Monthly review of complaints from clinicians and other healthcare providers regarding the quality of the testing to confirm the clinical efficacy of testing
4. Monthly evaluation of errors if identified
5. Monthly evaluation of corrective actions taken if identified
6. Media receipt and storage guidelines are reviewed annually and updated as necessary
7. IQCP reviewed at least annually and revised as needed by the lab director or designee