Example # 6

IQCP for *C.difficile* DNA amplification assay

Test System: Illumigene *C.difficile*

Facility: EXAMPLE

Written by:

Date: 12/29/15

Implementation Date: _____

This risk assessment and IQCP plan has been approved by:

_____

on _____

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Historical Quality Review

- This lab has been using this molecular assay for detection of *C.difficile* toxins since April 2012
- External positive and negative controls are run with each new shipment/lot and monthly
- Each device contains an internal control well that controls for amplification inhibition, assay reagents, and sample processing effectiveness
- Quality Control: CLIA '88 requires a positive and negative control be run daily, or each day patient samples are run. Alternatively, an IQCP can be developed to modify frequency of QC strain testing.
- Processes to mitigate QC errors, patient testing/ reporting errors and delayed reports are addressed in this IQCP

Information Used to Conduct Risk Assessment

1. Specimen
    - The following policies/procedures were reviewed:
        1. Patient/ Specimen Identification Policy (section 2.9)
        2. Specimen Identification and General Acceptability Criteria (section 2.12)
        3. Quality Control Protocol & Acceptability Criteria (section 2.2)
        4. Collection and Care of Microbiology Specimens (section 2.121)
2. Test System/Reagents
    - Package inserts containing testing principle and procedure, QC recommendations, and limitations from the manufacturer (Illumigene) were reviewed
    - Procedure reviewed*: Clostridium Difficile* DNA Molecular Assay (section 12.1)
    - QC data was reviewed for the following time frame: January to December 2015
    - Daily QC log documenting *Illumipro*-10 temperature,*Illumipro*-10 self-check test, temperature of heating block, time of incubation, and daily cleaning
    - New lot/shipment and monthly QC results
3. Test Personnel

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- The following policies/procedures were reviewed:
    1. Competency Assessment for Laboratory Testing Personnel 2.20. Competency Assessment (CA) is performed 6 months after initial training and annually thereafter. Documentation filed in Manager's office.
    2. Microbiology CAP Specimen Handling 2.1
    3. Competency documentation is located in the Manager's office
    4. CAP Proficiency Testing (PT) surveys for 2015 were reviewed

4. Environment

- Review of daily temperature/ humidity checks for the microbiology lab for the time period January 01,2015 to December 15,2015
- Policy for Temperature Monitoring (section 2.13)

Risk Assessment Summary

1. Review of the Daily QC log showed no out of range results
2. Temperature records show no out of range results
3. There was one corrected patient report where the result was initially reported as negative but was actually positive. Error was detected immediately by tech entering result. Patient impact was negligible

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Risk Assessment

Determination of Risk Level Scale

	Severity of Harm			
Probability of Harm	**No Risk**	**Low (not requiring medical intervention)**	**High (impairment requiring medical intervention)**	**Critical (permanent impairment requiring medical intervention)**
Frequent (1/week)	Acceptable	Not acceptable	Not acceptable	Not acceptable
Probable (1/month)	Acceptable	Acceptable	Not acceptable	Not acceptable
Occasional (1/6-12 months)	Acceptable	Acceptable	Acceptable	Not acceptable
Unlikely (once every 2/3 years)	Acceptable	Acceptable	Acceptable	Acceptable

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Table 1: Risk Assessment- Measures to Control Pre-Analytical Risks

Risk Factor	Possible Error	How can sources of error be reduced?	Risk Level with solutions in place
Specimen			
Patient identification	Failure to cross check name	-Adhere to procedures 2.9, 2.12, 2.2, 2.121 addressing patient identification specimen collection by source, labeling, transport, storage -Refer to Specimen section of procedure 12.1 *C.difficile* Molecular Assay -Competency assessment performed	Acceptable. Procedure in place for verifying patient ID using 2 identifiers
Collection/container/volume	Stool in unacceptable preservative		Acceptable - stools collected in wrong container are rejected.
Specimen integrity/quality/volume	Specimen contaminated with urine Formed stool Inadequate volume		Acceptable - stools contaminated with urine, formed stools and stools of inadequate volume are rejected.
Storage	Stools not run same day and left out at room temperature.		Acceptable - procedure in place for storage and specimen rejected if not stored properly.

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Table 2: Risk Assessment- Measures to Control Analytical Risks

Risk Factor	Possible Error	How can sources of error be reduced?	Risk Level with solutions in place
Testing Personnel:			
Training	Improper training can cause failed runs and delays in reporting results	During initial training and competency testing, emphasize the key aspects of running assay, Illumipro 10 self- checks, maintenance, cleaning, entering results	Acceptable – training is completed and competency is checked prior to tech performing and reporting patient results.
Competency	See above	See above	
Proficiency Testing	Incorrect results on CAP surveys	See above	Acceptable – Review of CAP survey results shows no errors in testing for the past year.
Reagents:			
Shipping receiving/storage	Testing kits left in inappropriate storage location or refrigerator where kit was stored malfunctions	Testing kit should be refrigerated upon arrival (2-27°C). Refrigerator has daily temperature documented in log. Kits in use are stored at room temperature. Daily room temperature is documented. Internal controls detect reagent integrity	Acceptable– Logs record temperature, proper storage emphasized in training, and internal controls detect failure of reagents. Kit not used if internal controls fails.

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Expiration Dates	Kit used beyond expiration date	Expiration dates are checked and documented every time a patient sample is run	Acceptable – kits are not used beyond expiration dating
Preparation/Use	Improper training on how to run test may cause DNA contamination, or specimen crossover	Techs are trained in proper molecular practices, specimens processed under a safety hood, daily cleaning logs kept	Acceptable - competency assessment performed and proper training done before techs run and report live patient specimen results.
Environment:			
Electric	Equipment failure (power outage)	Instrument can't be used if there isn't electricity.	Acceptable
Temperature of testing area	Temperature maintained in lab and temperature documented	Temperature of lab is documented daily	Acceptable - no temperature issues during the past year
Ventilation	Excessive dust interferes with optics in instrument	Staff instructed to keep lids closed unless loading devices to prevent dust from entering optics	Acceptable – no dust issues. Internal checks done by instrument on optics
Test System:			
Sample preparation	Inadequate training may lead to incorrect use of testing reagents/	During initial training and competency testing,	Acceptable - competency assessment performed and proper training done before techs run and report live

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Reaction buffer Test Device Sample collection brushes Heat treatment tubes	devices	emphasize the key aspects of running assay, *Illumipro* 10 self- checks, maintenance, cleaning, entering results	patient specimen results.
Heating block/thermometer	Incubator not at 95 +/- 5 °C. Heat treatment step not performed appropriately	Internal control monitors sample processing effectiveness	Acceptable - no temperature issues during the past year
Illumipro-10 instrument	• Software failure • Dirty optics • Scratches	• Illumipro 10 performs a self- check with every run, documented on daily log • Optical verification performed monthly, documented on log • Empty well check performed with each run	Acceptable - instrument self- checks detect issues

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Table 3: Risk Assessment- Measures to Control Post-Analytical Risks

Risk Factor	Possible Error	How can sources of error be reduced?	Risk Level with solutions in place
Test Results:			
Transmission of results to Electronic Health Record	• Incorrect results entered manually • Delay in entering results	• Manager maintains summary of corrected reports for review • Importance of proper result entry emphasized in Competency Training checklist • Retraining as appropriate	Acceptable - competency assessment performed and proper training done before techs run and report live patient specimen results.

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Quality Control Plan (QCP) for *C.difficile* Illumigene

1. Perform external QC (positive and negative controls) on each new lot/ shipment and monthly on Illumigene *C.difficile* kits before or concurrently with placing these materials into use for testing patient isolates
2. Document instrument checks: daily temperatures, instrument self-check test results, minutes of heat treatment, and daily cleaning of test system
3. Instrument, QC testing, or patient testing issues/ failures are brought to the attention of the supervisor or designee for immediate investigation
4. Patient specimen quality is evaluated for acceptability before testing. Unacceptable specimens are canceled.
5. Alerts and bulletins by manufacturer will be reviewed and acted on appropriately as necessary
6. Training and competency of testing personnel is kept up to date
7. Proficiency testing (PT) failures are addressed as soon as possible

Quality Assessment: Ongoing Monitoring for QCP Effectiveness

1. Documented review of QC will be performed by supervisor or designee monthly to ensure QC is accurately performed and documented
2. Documented review of equipment maintenance and function checks at least monthly by supervisor or designee
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. Review of staff training and competency assessments carried out according to standard laboratory protocols
7. Regular review of Proficiency Testing results
8. IQCP reviewed at least annually and revised as needed by the lab director or designee