Microbiology and Molecular QC

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Objectives

- Refer to QC SOPs in the Microbiology Department at ATL VAMC
- Review QC procedures/correct documentation for Microbiology and Molecular "New Shipments and New Lot Numbers"
- Review proper frequency of Microbiology and Molecular QC testing

VHA MISSION

Strategic Plan 2013-2018:

"Honor America's Veterans by providing exceptional health care that improves their health and well-being."

VHA Principles

VHA Strategic Plan 2013-2018:

VHA Principle:

"CONTINUOUSLY IMPROVING"…everyday service to our veterans

Guidance

- CLIA
- CAP
- VAMC mandates; Chief of Pathology may add additional procedures as warranted

(Pathology holds the lab CLIA certificates)

SOPs

Overarching SOPs:
QUALITY CONTROL and QUALITY IMPROVEMENT

MI-001-12
(contains definitions, frequency of QC/PMs, and expected results of microbiology and molecular QC platforms)

LAB GEN (contains specific information on corrective actions – occurrence reporting, **Check Point** use, and other general laboratory)

CHANGE

“The Only Thing That Is Constant Is Change -”
— Heraclitus (Greek philosopher, 500 B.C.)

NEW CAP Individualized QC PLAN (IQCP) requirements … refer to CAP letter.

Definitions

external controls: *Levels of controls (positive/negative for qualitative testing, or high/mid-range/low levels for quantitative testing) included with kits or made up from known ATCC strains for use in QC testing. External controls are run like patient samples, and are independent of the assay itself.*

internal controls*: Controls lie within the test matrix (dependent of the assay), allowing for a reliability (self-check) of the test process. In many kits, qualitative tests, and PCR test procedures, the internal controls are designed to detect deficiencies in the analytical process prior to the release of patient results.*

surrogate controls: *Controls most like the patient test itself, undergoing the same or similar collection and processing method, representative of the same test matrix as a patient sample, and representative of the ranges of expected results. For example, known patient samples or CAP proficiency survey samples may be retained for use as surrogate controls. Surrogates function much like external controls, in that they must reflect the range of results to be encountered*

30-day QC*: PER CAP…required for all molecular test procedures (QUALITATIVE and QUANTITATIVE). Positive and negative (QUAL) or high and mid-range level (QUANT) testing must be performed at least every 30 days using external controls and surrogate controls (for QUANT). Also required for Fecal Lactoferrin and Rapid Streptococcus A test kits.*

cross-check QC: *Used for testing kit reagents of new lots, or new shipments. External controls or surrogate controls are used to check performance of the new lot/shipment against reagents from the last lot (or other previous lot) PRIOR to (or concurrent with) placing the new reagents in service. Per CAP: Cross check is REQUIRED for ALL EIA TEST KITS. (Quantiferon is included in this category.)*

new box opened QC*: External controls included with kit are used to QC every new kit when placed in service. This is not the same as cross-check.*

New shipments – What to do?

1. Sign for shipment AFTER checking to be sure it is for our department
2. Sign-in product name (actual number of items received), vendor name, PO#, date/your initials
3. Go directly to QC CLIPBOARD to log-in the items that require QC.
4. IMPORTANT!! Pull the REMEL pack slips (one for each Remel location) and make copy for media QC book. Stamp, date, initial, place in QC MEDIA notebook.

Microbiology

Bacteriology

- Daily/weekly QC sheet
- Gram Stain QC notebook (remember, new form!)
- Media
- New reagents
- Rapid Tests (Flu, Strep A, Fecal Lactoferrin)
- Vitek (new lot *CERTIFICATE of CONFORMANCE*)

"In use" date must be documented on the item and on the REAGENT QC SHEET(DIFFERENTIAL TEST, MEDIA, VITEK, STAIN, FIT clipboard, etc.).

Other Stains

- India Ink: Each use; also with NEW LOT / NEW SHIPMENTS
- Lactophenol Aniline Blue: NEW LOT/NEW SHIPMENT
- Parasitology - Merifluor: With each use
- Parasitology -Trichrome: New reagents (monthly) and with EACH batch – two different forms
- Any others?

EIA reagents/ Quantiferon

In addition:

Requirement/SOP states to perform cross-check between new lots/shipments and lot in use.

Use surrogates (previous pos/neg patients or CAP survey specimens)

Document in a way that someone reading the printouts can follow that this is your cross-check.

Mycology

- Special Media:

"Each lot or shipment of Corn Meal Agar with Tween 80 is tested before use."

Molecular

Molecular Tests – **QUALITATIVE (AFFIRM and CEPHEID analyzers)** (BD **Affirm** – **multiplex** test, MRSA-Cepheid, CDIF-Cepheid, Multiplex FLU-Cepheid)	• **30-day** external QC on **lot in use** • Internal QC with each patient test • **QC** each new lot/new shipment using external QC **PRIOR** to placing a lot in use (note: cannot use a surrogate patient for Affirm or MRSA; may use a surrogate patient specimen for CDIF); test one kit only (of the batch). Must also be performed after instrument software update or major maintenance.
Molecular Tests – **QUALITATIVE** (ROCHE CT/NG platform: 4800)	• **External** QC is always on board with each run. No need for 30-day QC. • QC each new lot/new shipment of detection reagents with **surrogate** patient specimens analyzed using a prior lot number (positive for CT/NG, negative for CT/NG). • Internal QC is automatically on board with each patient test
Molecular Tests – **QUANTITATIVE** (ROCHE HIV PCR viral load)	• **30-day** external **SURROGATE** QC on **lot in use (Acrometrix 3 levels)** • **QC** each **New lot/new shipment** using external (saved, frozen) surrogate QC and a “TND” surrogate tested previously with the last reagent lot in use (test one run of one kit only of the lot/shipment) • Internal QC automatic with each patient test • External QC on board with each PCR run • **AMR/LINEARITY VERIFICATION every 6 months (using CAP linearity kit)**

Linearity / CAL-ver

6 month Calibration Verification (linearities) on quantitative systems:

- HIV PCR
- EIA plate reader
- Quantiferon plate reader

- How? Use HIV and EIA SOPs and CAP survey instructions. Be sure to go to I-drive, CAP folder to enter linearity into the designated Excel graph – we want to be sure we are linear (no clerical errors) before sending results to CAP.

Pause to Review

- What is a *surrogate* control?
- What does *MULTIPLEX* mean?
- What is difference between *Qualitative* molecular testing and *Quantitative* molecular testing?

Examples of Occurrences

- Cepheid 30 day QC: No QC report printouts from instrument
- TM media placed in use, but never QC'd and never documented with date "placed in use"
- Rapid kits placed "in use" but **no** NEW LOT / NEW SHIPMENT QC documented
- Temp charts / Daily-weekly QC charts with **blanks**
- Daily QC chart: Bench decontamination – **"X"** if not in use – is missing from chart

Corrective Actions

- In-services
- Documentation of retraining post-CAP inspection
- Reminders and stickers placed on kits after new lot/ new shipment QC has been performed
- What other items can we think of with regard to CORRECTIVE ACTIONS? Preventing errors?
- Be aware of situations where the LOT QC number is different between bottle and box of bottles. Document both lot numbers if in question. (EX: Staph latex reagent)
- Be aware of media shipments – same media received from different locations, but on same day…

Open Discussion

- Any QC Questions?
- QC items that we did not mention?

(BC bottle QC certificates… from SPD; Occult blood guiac cards/developer from SPD)

*Report all concerns, suggestions, occurrences to the microbiology supervisor.

EVERYONE is responsible for QC! Look at each item with an INSPECTOR's eye…

Thank you

Post-test