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| **Microbiology/Virology QC Policy** |
| **Principle and Clinical Significance** | This policy provides QC Guidelines for the Microbiology and Virology Labs. The QC program ensures that the information generated by the Bacteriology/Virology Laboratory is accurate, reliable, and reproducible. This is accomplished by assessing the quality of the specimens; monitoring the performance of test procedures, reagents, media, instruments, and personnel; reviewing test results; and documenting the validity of the test method. Personnel who perform routine testing must test quality control specimens in the same manner as patient specimens. |
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| **QC Parameters** | 1. **Personnel**
* Test for visual color discrimination in pre-employment physical exam
* Document competency and training.
* Document continuing education.
* Employee must attend department meetings and/or read meeting minutes.
* Provide employees with written performance standards.
* Perform employee evaluations annually.
* Personnel records are held for 5 years post termination.
1. **Policy and procedure manual**
* Write in CLSI format.Contains test principal, safety, specimen type, materials and reagents, QC, assay procedure, results and interpretation, reporting, training/competency, notes/limitations and references.
* Medical director, department lead or designee will review and initial at least biennially.
* Medical director or department lead tech reviews new policies and procedures, as well as major revisions before implementation.
* If there is a change in directorship, the new director will review the policy/procedure manual within 12 months of change.
* Testing personnel are required to review new or revised procedures. They must acknowledge that they are knowledgeable of the procedure contents by initialing the procedure review document.
* Retain discontinued procedures for 2 years. Document date of retirement.
1. **Records/Reports/Specimen Retention**
* Record all QC results on appropriate QC form.
* Document failed QC results and corrective action by sending Sunquest mailbox notification or in QC logbook.
1. Repeat test.
2. If the test remains out-of-control, repeat the test with new reagents and/or fresh QC organism. Notify Bacti/Viro lead MLS.
3. Perform alternate testing if the problem remains unresolved.
4. Do not report patient results until the problem is resolved.
* Report patient results to authorized personnel only in compliance with HIPPA regulations.
* Report critical values immediately. Document person notified of value, date and time.
* Document any failed attempts to notify appropriate person of a critical value and action taken. File an on-line Safety report.
* Review patient reports before filing in Sunquest for patient identification, clerical errors, significant analytical errors and unusual laboratory results.
* Review completed worksheets for accuracy.
1. If erroneous results have been reported, contact the physician and issue a corrected report.
2. Do not remove the erroneous report from the patient’s chart.
* Correct errors in patient reports in a timely fashion. Document person notified of error, date and time.
* Include name of reference laboratory on patient’s report.
* Document reasons for specimen rejection if it is unacceptable.
* Retain records for 2 years including test requisitions; instrument printouts (Vitek, MicroScan, Sofia), rapid testing worksheets and QA/QC records.
* Specimens of CSF and body fluids are retained 7 days. All direct Gram stain slides are retained 7 days.
* Urine specimens are saved in the Core lab for 24 hours.
* Safety reports are electronically maintained by Children’s Risk Management.
1. **Equipment**
* Function checks of equipment are performed and records maintained by the BioMed department.
* Service contracts: Instrument PMs are performed annually by the company field service engineers or at recommended intervals dependent upon the contract.
* Document routine preventive maintenance.
* Maintain the records for the life of the instrument.
1. **Commercially prepared media exempt from QC**
* Retain manufacturer’s QC protocol.
* Assurance that manufacturer follows CLSI standards is available on-line or upon request.
* Inspect each shipment for cracked media or Petri dishes, hemolysis, freezing, unequal filling, excessive bubbles, and contamination.
* Document medium deficiencies and corrective action; inform manufacturer.
* Discard outdated media that have exceeded their expiration date.
1. **Nonexempt media**
* Inspect each shipment for cracked media or Petri dishes, hemolysis, freezing, unequal filling, excessive bubbles, and contamination.
* Test each new lot or shipment of media with known QC organisms for the ability to support growth, proper hemolytic and biochemical reactions.
* Record QC results in QC logbook. Document deficiencies and corrective action; inform manufacturer.
* Discard outdated media that have exceeded their expiration date.
1. **Defined water types**
* Clinical Laboratory Reagent Water (CLRW) available from the DI H2O faucet is used for preparation of PBS wash buffers in microbiology and virology. Resistivity testing is performed daily by Chemistry. Refer [to CH 5.60 Millipore Maintenance Procedures](http://khan.childrensmn.org/Manuals/Lab/SOP/Chem/Procedure/201788.pdf). Testing for microbial content is done weekly by microbiology. Refer to [MC 8.3 Water Culture Procedure](http://khan.childrensmn.org/Manuals/Lab/SOP/Micro/QC/209876.pdf)

Water quality testing documentation is retained in the Chemistry Section.* Sterile Commercially Bottled Purified Water (CHC# 8638 Gibco) is used for rehydrating lyophilized reagents where water is the specified diluent.

The manufacturer tests for conductivity, total organic carbon, endotoxin, bioburden and metals. Certificates of Analysis are retained in the virology section.

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1. **Stains, reagents, chemicals and antisera**
* Label containers as to contents; storage requirements; concentration; date prepared or reconstituted by laboratory; received and placed in service, and expiration date.
* A new expiration date MUST be recorded on the reagent, if opening or reconstitution changes the expiration date.
* If no expiration date is indicated by the manufacturer for a chemical or reagent, evaluation for product deterioration (color change, non-reactivity) must be done prior to each use. The lab will assign an expiration date based on known stability, frequency of use, storage conditions and risk of deterioration,
* Store according to manufacturer’s recommendations.
* Test each new lot or shipment with positive and negative controls before use.
* Record QC results in QC logbook. Document deficiencies and corrective action; inform manufacturer.
* Discard outdated reagents and reagents that have exceeded their indicated expiration date. .
1. **Commercial test kits**
* Test each new lot or shipment with QC reference material before placing into service or concurrent with use. The intent is to ensure that the new and previous lots yield a similar result. Testing may be done by:
1. Direct analysis of reagent with a suitable reference material, i.e., a known patient specimen and kit controls.
2. Parallel testing with the old reagent lot, i.e., old controls/new reagents tested with new controls/new reagents.
* Record QC results in QC logbook. Document deficiencies and corrective action; inform manufacturer.
* Discard outdated test kits that have exceeded their expiration date.
1. **Proficiency testing**
* Participate in CAP or WSLH proficiency testing program. Identify to the same level as patient samples.
* Perform semi-annual alternate proficiency testing when CAP testing materials are not available.
1. **Test verification**
* Perform prior to test implementation.
* Determine sensitivity, specificity, predictive values, accuracy, and precision as compared to reference method.
1. **Test validation**
* Document ongoing performance of verified test.
1. Test patient samples in parallel with an established test.
2. Test known specimens.
3. Compare results with the patient diagnosis by chart review.
	* Use QA and QC data.
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| **General Information and Frequency of Testing** | 1. **QC stock organisms**
* QC organisms are ATCC strains that are well characterized.
* Maintain QC organisms at -50°C for 1 year.
* Subculture and refreeze annually.
1. **Commercially prepared media**
* Date media when received.
* Record lot number, date and quantity received in Media QC logbook.
* Store according to manufacturer’s instructions.
* Perform QC on each new lot or shipment in parallel with the current lot before use.
* Rotate media weekly to use the oldest first.
* Record QC results and macro appearance in QC logbook.
* Evaluate media condition prior to use: within expiration date, plates smooth, adequately hydrated, uncontaminated and appropriate color and thickness. Check that tubed media is not dried or loose from sides.
* Discard outdated media, cracked/dried media, deteriorated media, or media that has failed QC.
* Document deficiencies and corrective action. Notify Microbiology Supervisor.
1. **Antisera**
* Date container when received.
* Record lot number, date, and quantity received in QC logbook.
* Store according to manufacturer’s instructions.
* Perform QC on each new lot or shipment in parallel with the current lot before use and every 6 months thereafter.
* Record QC results in new inventory QC logbook.
* Date container when put into use. Record in QC logbook.
* Discard outdated or contaminated antiserum.
* Discard antiserum that has failed QC once the manufacturer has been notified. The company may request that the antiserum be returned for further investigation.
* Document deficiencies and corrective action. Notify Lead MLS.
1. **Stains**
* Date container when received.
* Record lot number, date, and quantity received in QC logbook.
* If no expiration date is indicated by the manufacturer, the laboratory will assign an expiration date based on known stability, frequency of use, storage conditions, and risk of deterioration.
* Store according to manufacturer’s instructions.
* Perform QC on each new lot or shipment in parallel with the current lot before use or concurrent with use. Test for positive and negative reactivity.
* Record QC results in QC logbook.
* Date container when put into use. Record in QC logbook.
* Discard stains that have failed QC once the manufacturer has been notified. The company may request that the reagents be returned for further investigation.
* Document deficiencies and corrective action in new inventory QC logbook. Notify Lead MLS.
* Perform daily/weekly QC testing after stain has been “put into use” as follows:

a. Gram stain weekly b. Trichrome stain weeklyc. Ziehl-Neelsen stain day of use d. Fluorescent antibody stains day of usee. Acridine orange stain day of use* Record daily/weekly QC testing on the Daily QC log.
* Document deficiencies and corrective action.
* Discard outdated or contaminated stains.
1. **Reagents**
* Date container when received.
* Record lot number, date, and quantity received in QC logbook.
* If no expiration date is indicated by the manufacturer, the laboratory will assign an expiration date based on known stability, frequency of use, storage conditions, and risk of deterioration.
* Store according to manufacturer’s instructions.
* Perform QC on each new lot or shipment in parallel with the current lot before use or concurrent with use. Test for positive and negative reactivity.
* Record QC results in QC logbook.
* Date container when put into use. The new expiration MUST be recorded if opening or reconstitution changes the original expiration date. Record in logbook.
* Discard reagents that have failed QC once the manufacturer has been notified. The company may request that the reagents be returned for further investigation.
* Document deficiencies and corrective action. Notify Microbiology Supervisor.

Additional QC testing:* Perform Tube Coagulase QC testing on each day of use
* Record daily QC testing on the Daily QC log. Document deficiencies and corrective action by sending Sunquest mailbox notification*.*
* Discard outdated or contaminated reagents.
1. **Commercial kits**
* Date kit when received.
* Record lot number, date and quantity received in QC logbook.
* Store according to manufacturer’s instructions.
* Perform QC on each new lot or shipment in parallel with the current lot before use or concurrent with use. Perform QC as specified by the manufacturer thereafter. Test for positive and negative reactions.
* Record QC results in QC logbook.
* Date kit when put into use. Record in logbook.
* Discard kits that have failed QC once the manufacturer has been notified. The company may request that the kit be returned for further investigation.
* Discard outdated test kits.
* Document deficiencies and corrective action new inventory QC logbook. Notify Microbiology Supervisor.
* Components of a reagent kits can only be used with the same lot to ensure proper function of the test. The components cannot be interchanged with those of another kit of a different lot number unless specified by the manufacturer.
1. **Susceptibility tests**
* Date MH agar, KB disks, MIC panels, and Vitek cards when received.
* Record lot number, date and quantity received in QC logbook (record Vitek cards in Vitek QC program).
* Store according to manufacturer’s instructions.
* Perform QC testing each time a new lot or new shipment of materials (MHA, disks, MIC panels/cards) is put into use.
* Perform weekly Vitek MIC AST QC, MicroScan NC32, PC20, MicroStrep AST QC and KB gram pos, gram neg and Pseudo disk diffusion QC, manual Dtest, ESBL and Penicillin Etest QC.
* Record the weekly QC results in QC logbooks or print out the Vitek reports. Each organism must be checked for deviations, initial and date all results and place in the Vitek QC notebook.
* If an out of QC range deviation is obtained, repeat the QC test the same day.
* Patient test results obtained in while QC is under investigation or performed since the last acceptable QC results, must be re-evaluated to determine if there is a significant clinical difference in results. Document these findings and report to Micro Supervisor/Medical Director.
* Each month QC data will be reviewed and assessed by the Micro Supervisor, or designee.
* Date MIC panels when put into use. Record in MIC QC logbook and Vitek QC program. “Date in Use” documentation is no longer required in the Vitek 2 QC program.
* Perform QC for 20 or 30 consecutive days to validate all new MIC panels and Vitek cards before going to weekly QC. No more than 1 out 20 or 3 out of 30 results can be outside the acceptable limits.
1. **Virology cell lines**
* Have available the appropriate cell lines for isolation and identification of viruses related to diagnostic services offered.
* Record lot number, date, and quantity received in QC logbook.
* Examine each shipment of tubes, shell vials and cluster plates for breakage.
* Store according to manufacturer’s instructions.
* Observe monolayer of each new lot or shipment microscopically to confirm that cells are attached to the substratum, confluency is appropriate and that cell appearance is typical.
* Upon receipt, examine cell lines for endogenous viral contamination. Continue to monitor during use. Document any foamy virus or monkey virus in PMK tubes in QC logbook. Evaluate suitability for isolation.
* Check that cell culture media is clear and free of contamination and near a neutral pH (salmon pink in color).
* Perform QC on each lot or shipment with uninoculated control and for correct CPE using the appropriate viruses for each cell line.
* Record QC results in QC logbook.
* Discard cell lines that are contaminated, have broken tubes or have failed QC. Notify manufacturer.
* Rotate cell lines weekly
* Document deficiencies and corrective action. Notify Lead MLS.
1. **Fetal Bovine Sera**
* Check new lots for cytotoxicity prior to use by inoculating 3 MRC-5 tubes with 0.2ml of FBS each and incubating for 7 days. Examine daily for toxicity. Record results at 7 days. Do not put FBS into use if excessive toxicity is noted and notify manufacturer.
1. **Equipment**
* **Anaerobic jars**
1. Use anaerobic indicator with each use.
2. Record results of anaerobic indicator checks on daily maintenance form.
3. Check jars and lids for damage daily.
4. Clean jars periodically.
5. Document any corrective action by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results. Notify Micro Supervisor.
* ***Campylobacter* jar**
1. Use a biological indicator daily to check atmospheric conditions. This will consist of a tri-plate inoculated with *Clostridium perfringens, Pseudomonas aeruginosa* and *Campylobacter jejuni.*
2. Record results on daily QC form.
3. Check jars and lids for damage daily.
4. Clean jars weekly.
5. Document any corrective action by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results. Notify Micro Supervisor.
* **CO2 Incubator**
1. Daily check CO2 atmospheric content from incubator display for each CO2 Incubator. Record results on the daily maintenance/temp chart form.
2. Weekly check CO2 atmospheric content with Fyrite CO2 gas measuring device. Record results on the daily maintenance/temp chart form.
3. Check atmospheric conditions in microbiology incubators using a biological control (*Neisseria gonorrhoeae)* daily and record.
4. Record CO2 gas content in cylinder. Replace tank at approximately 400 lb.
5. Clean bimonthly.
6. Document any corrective action by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results. Notify Micro Supervisor.
* **Gas tank regulator**
1. Check tank pressure daily.
2. Record on daily maintenance form.
3. Document any corrective action by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results. Notify Micro Supervisor.
* **Thermometers**
1. Smart Temps, a remote monitoring system monitor’s temperature dependent equipment including refrigerators, freezers, and incubators. The system is continuously monitored and Smart Temps functionality is accessed from the Applications on Children’s intranet. Password is: microm
2. Check non-certified thermometers against NIST standard before putting into use. Record in Thermometer Manual.
3. Digital thermometers: Place Traceable Certificate of Calibration in Thermometer Manual. Recertify calibration before expiry date.
4. Check for damage daily.
5. Document any corrective action by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results.
* **Temperatures**
1. Smart Temps, a remote monitoring system monitor’s temperature dependent equipment including refrigerators, freezers, and incubators. The system is continuously monitored and Smart Temps functionality is accessed from the Applications on the Children’s intranet. Password is: micorm
2. Temperatures of all non Smart Temps monitored incubators, refrigerators, freezers, heat blocks, water baths, and ambient temp are recorded daily (beginning of day shift) on the daily maintenance form.
3. Document deficiencies and corrective action by sending Sunquest mailbox notification*.* It must be noted if the failure affected patient test results. Notify Micro Supervisor of trending or temperatures that are out-of-range.
* **Microliter pipettes**
1. Check for accuracy before being placed in service and every 6 months.
2. Use PSC pipette calibration system.
3. Document any corrective action on the by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results. Notify Micro Supervisor.
* **Calibrated loops**
1. Check calibration monthly.
2. Document deficiencies and corrective action.
* **Biological safety cabinets**
1. Certified annually
2. Check exhaust failure system daily and record on daily maintenance form.
3. Clean gutter area monthly.
* **Ocular micrometer**
1. Available and calibrated each time eyepieces or objectives are changed.
* **Bactec FX (MPLS & STP)**
1. Station QC occurs automatically every 10 min when a bottle is entered into the system.
2. Record temps daily.
3. Check station and panel indicators daily.
4. Change filters weekly.
5. Preventive maintenance is performed annually.
6. Document any corrective action by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results. Notify Micro Supervisor.
* **Centrifuge**
1. Clean monthly or as needed.
2. Balance load with each use.
* **Incinerator burner**
1. Inspect heater element for cracks or fissures. Replace as needed.
2. Document deficiencies and corrective action.
* **Microscope**
1. Clean lenses; remove oil daily or as needed.
2. Cover at the end of each day to protect from dust.
3. Clean and inspect all parts and realign annually
* **Water bath**
1. Check temp, water level, and for contamination daily.
2. Drain and clean monthly
* **Vitek 2**
1. Temperature and optics checked 3 times daily and recorded by instrument. Temperature and optics report printed out monthly.
2. Record instrument status, empty waste tray, and flush saline daily.
3. Saline sterility checks performed weekly.
4. Instrument components cleaned at approximate monthly intervals.
5. Preventive maintenance is performed twice annually.
6. Document any corrective action by sending Sunquest mailbox notification. It must be noted if the failure affected patient test results. Notify Lead MLS.
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| **References** | 1. Isenberg, Henry D., *Essential Procedures for Clinical Microbiology,* 1998, ASM Press, Washington, D.C., pg. 737-743.
2. Jenkins, S.G., Section editor, Quality Assurance, Quality Control, Laboratory Records, and Water Quality, Section 14 in *Clinical Microbiology Procedures Handbook,* Garcia, Lynne. Editor, 2010, ASM Press, Washington, D.C.
3. CLSI publication M41-A Vol. 26 No.35, *Viral Culture; Approved Guideline* *[*ISBN 1-56238-623-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2006.
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| **Appendix** | * 1. QC and Equipment Failure Log [G:\LAB\Microbiology\micro forms\QC Forms\QC and equipment failure log.doc](file:///%5C%5Ckidsnet.childrenshc.org%5Cchcdfs%5Cdept%5CLab%20Procedures%5CMicro%20Procedure%20Manuals%5CMicrobiology%5Cmicro%20forms%5CQC%20Forms%5CQC%20and%20equipment%20failure%20log.doc)
	2. Media QC Worksheet [G:\LAB\Microbiology\Micro Folder\Inventory and QC\Quality Control worksheet for Media.doc](file:///%5C%5Ckidsnet.childrenshc.org%5Cchcdfs%5Cdept%5CLab%20Procedures%5CMicro%20Procedure%20Manuals%5CMicrobiology%5CMicro%20Folder%5CInventory%20and%20QC%5CQuality%20Control%20worksheet%20for%20Media.doc)
	3. Reagent QC Worksheet [G:\LAB\Microbiology\Micro Folder\Inventory and QC\QUALITY CONTROL WORKSHEET REAGENT.doc](file:///%5C%5Ckidsnet.childrenshc.org%5Cchcdfs%5Cdept%5CLab%20Procedures%5CMicro%20Procedure%20Manuals%5CMicrobiology%5CMicro%20Folder%5CInventory%20and%20QC%5CQUALITY%20CONTROL%20WORKSHEET%20REAGENT.doc)
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Pat Ackerman | 02/06/1982 | Initial Version |
| 1.1 | Pat Ackerman | 09/17/1999 |  |
| 1.2 | Pat Ackerman | 09/17/2001 |  |
|  | 1.3 | Pat Ackerman | 09/03/2003 |  |  |  |
| 1.4 | Pat Ackerman | 08/26/2005 |  |
| 1.6 | Pat Ackerman | 12/20/2006 | Modified Thermometer section to include digital thermometers. Updated susceptibility weekly validation. |
| 1.7 | Pat Ackerman | 07/06/2007 | Added notification if patient results were affected by deficiencies. Title change from dept. supervisor to technical specialist. Revised antisera and reagent QC; eliminated daily QC for bacitracin, optochin and XV strips, Changed monthly QC for antisera to 6 months, trichrome stain changed from daily to weekly. Added Vitek 2 under Equipment section. Updated ProbeTec environmental culture to weekly rotation from monthly. |
| 1.8 | Pat Ackerman | 09/20/2007 | Added ASR information, #8 in QC parameters and General Information. Added EasyQ to equipment. Changed the policy name from *Quality Control Guidelines* to *Quality Systems.* Title change from Technical Specialist to Lead Tech. |
| 1.9 | Helen Stefan | 09/14/2010 | Virology cell line section: examine for breakage, endogenous viruses. Prepared media section: Evaluate media condition prior to use |
| 1.10 | Helen Stefan | 06/13/2011 | Added FBS cytotoxicity check, removed Nuclisens EasyQ and ASR --> in molecular, removed Vitek32—no longer in use, added BACTEC FX, added check ambient temps daily in temp section |
| 1.11 | Helen Stefan | 09/21/2012 | Removed BD ProbeTec—no longer in use, added assigning expiration date to reagents that do not have a manufacturer provided expiration date. |
| 1.12 | Becky Carlson | 5/05/2013 | Added Isensix temperature monitoring language to Thermometer and Temperature sections. Added Specimen retention requirement language. |
| 1.13 | Tina Gronquist | 07/28/2014 | Updated into online format |
| 2 | Helen Stefan | 4/2/2015 | Renumbered Procedure from MC801 to MCVI1.1, changed version to whole number, removed authorization and annual review table for CMS upload. |
| 3 | Becky Carlson  | 9/22/2015 | Updated Reagent, Media, Stain, Chemicals and Antisera sections regarding expiration dates/discard.Updated “out of QC range results”, to be repeated same day, and documentation of possibly affected patient results. |
| 4 | Helen Stefan | 10/1/15 | Added Defined water types to comply with CAP GEN.41500 |
| 4 | Susan DeMeyere | 6/23/2017 | Removed Flagella & Auromine-Rhodamine stains. Removed Isensix and added SmartTemps. Removed Bactec 9240  |
| **Archived by:** |  | **Archived Date:** |  |