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| Quality Review and Quality Control for Plated/ Tube Media and Bactec Bottles | | | | | | | | |
| **Purpose** | This procedure provides instruction for performing Quality Review and Quality Control of plated/ tube media and Bactec bottles. | | | | | | | |
| **Principal and Clinical Significance** | Each shipment of purchased media is examined for breakage, contamination, appearance and evidence of freezing or overheating.  Non-exempt media: An appropriate sample from each lot and shipment of each purchased medium is checked before  or concurrent with initial use for each of the following:   1. Sterility 2. Ability to support growth by means of stock cultures 3. Biochemical reactivity, where appropriate | | | | | | | |
| **Policy Statements** | This procedure applies to Microbiologists who perform Media QC. | | | | | | | |
| **Materials** | * 0.45% sterile saline * 75 x 12mm round bottom suspension tubes * 200 µl pipette and sterile tips * 0.001 ml calibrated loop * Inoculating needle * Densitometer * Control organisms (ATCC strains or well characterized lab strains, i.e. CAP survey isolates) | | | | | | | |
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| **Special Safety Precautions** | Microbiologists are subject to occupational risks associated with specimen handling.   1. [*Biohazard Containment*](file:///\\kidsnet.childrenshc.org\chcdfs\dept\Lab%20Procedures\Micro%20Procedure%20Manuals\MC%20200%20%20%20%20Safety\MC%20201%20%20%20Biohazard%20Containment.doc) 2. [*Biohazardous Spills*](file:///\\kidsnet.childrenshc.org\chcdfs\dept\Lab%20Procedures\Micro%20Procedure%20Manuals\MC%20200%20%20%20%20Safety\MC%20204%20%20%20Biohazardous%20spills.doc) 3. [*Safety in the Microbiology Laboratory*](file:///\\kidsnet.childrenshc.org\chcdfs\dept\Lab%20Procedures\Micro%20Procedure%20Manuals\MC%20200%20%20%20%20Safety\MC%20202%20%20%20Safety%20in%20the%20Microbiology%20Lab%20Policy.doc) | | | | | | | |
| **Exempt Media** | All media is examined for breakage, contamination, appearance and evidence of freezing and overheating. This is documented on each Quality Control Worksheets in the Media binder, specific for each media.   * Bactec Blood Culture Bottles will be supplied to the St. Paul lab from the Minneapolis lab. Minneapolis lab will perform the visual examination and document in the Media binder. | | | | | | | |
| |  | | --- | | **Individualized**  **Quality**  **Control Plans** | | **Manufacturer**  **Information** | | |  | | --- | | [IQCP for Commercially Prepared CLSI – Exempt Media (IQCP 1.00 )](http://khan.childrensmn.org/Manuals/Lab/SOP/MCVI/MCVI.asp) was implemented to  allow for the acceptance of the quality control performed by the media supplier for media listed as  “exempt” in the CLSI/NCCLS Standard M22-A3. | | “Certificates of Quality” (CoQ) are provided with each lot/shipment of exempt media which indicate  the specific lot of media has met performance specifications described in CLSI M22.   * Certificatesof Quality (CoQ’s) certify that specific lot numbersof exempt media have met all   performance and QC criteria for the product.   * CoQ’s can be accessed online, on the websites listed below. * No additional risks were identified from review of these Instructions for Use, alerts, or bulletins   associated with these media products.   * All alerts and bulletins pertaining to these medias can be found in the Microbiology media QC files.   BD / Remel have no recommendation for end-user QC of CLSI exempt media. See links:  **BD:** [BD / BBL Product Center](http://www.bd.com/ds/productCenter/221165.asp)  **REMEL:** [Remel.com Prepared Culture Media](http://www.remel.com/Catalog/Section.aspx?name=Prepared+Culture+Media)   * Package inserts indicate that manufacturer QC testing of exempt media includes use of QC strains   and procedures recommended in CLSI M22 and do not indicate that the user must perform further  testing with QC strains.   * Manufacturer informs users of any problems with exempt media that are identified subsequent to   release of the media with “product alerts”.   * Manufacturer has hotline available for reporting problems with defective media.   + BD 1-800-638-8663 or Remel 1-800-255-6730 * Package inserts, CoQ’s and product alerts can be found at the BD or Remel websites listed   in Manufacturer’s information. (See above)   * Expiration Date**-**Prepared plates stored in their original sleeve wrapping at2-8°C until just prior to   use may be inoculated up to theexpiration date and incubated for recommended incubationtimes,  including up to 6 weeks for mycology media and up to 8 weeks for mycobacteriology media. | | | | | | | | |
| **QC**  **for Commercially Prepared Media** | Commercially prepared medias are purchased from BBL and/or Remel Labs. For each lot, the  preparer has certified that quality control performance was acceptable, and maintains records of  lot numbers of media for at least 2 years. This information is available upon customer request.  Each sleeve of BBL brand prepared media states “Lot samples were tested and met product specifications and CLSI standards where relevant.”  The standards in Quality Control for Commercially Prepared Microbiological Media-- Approved Standard—Third Edition. NCCLS-- M22-A3. June 2004 are followed. Table 1B of the document lists the media that requires user QC.  Quality Control Worksheets in the Media binder, specific for each media, list the control organisms and the expected reactions.   1. Plated Media    1. Prepare a saline suspension of the control organism(s) equivalent to a 0.5 McFarland standard.    2. Label a blank tube with the organism name, ATCC identifier, date and dilution (1:10).    3. Make a 1:10 dilution of the prepared bacterial suspension into the labeled tube.       1. Pipette 200 µl of the 0.5 McFarland into 1.8 ml of saline.    4. Inoculate and streak the plates with a 0.001 calibrated loop.    5. Incubate the plate in the appropriate atmosphere.    6. After 24-48 hours, examine plates for satisfactory growth and colony size.    7. Record results in the Media QC log. 2. Tube Media    1. Inoculate directly with the test organism(s).    2. Incubate at 35ºC.    3. Examine after 24 hours or longer for typical reactions.    4. Record results in the Media QC log. | | | | | | | |
| **Unsatisfactory Results** | If unexpected results occur, proceed as follows:   1. Repeat test using new control organism(s). 2. If performance tests fail after repeat, the media is unacceptable for use. 3. Report all performance failures to the Microbiology Supervisor. 4. Contact technical services from which the media was purchased for replacement.    1. 1-800-638-8663 Technical Services - Becton Dickinson Microbiology Systems    2. 1-800-255-6730 Technical Services - Remel 5. Information required:    1. Product name and number    2. Lot number    3. Expiration date    4. Organisms used for testing    5. Results   Document findings on the QA/QC log and in the Media QC log. | | | | | | | |
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| **References** | 1. Versalovic, James. et. al., Manual for Clinical Microbiology, 10th Edition, 2011, ASM press, Washington, DC. 2. Quality Assurance for Commercially Prepared Microbiological Culture Media – Third Edition; Approved Standard, June 2004, M22-A2 Vol. 16 No. 16, NCCLS., Wayne, Pennsylvania 3. CAP Checklist MIC.21240 Media QC – Purchased 4. CAP Checklist MIC.21220 Inspection of Media Shipments | | | | | | | |
| **Appendices** |  | | | | | | | |
| **Training Plan/ Competency Assessment** | **Training Plan** | | | | | **Initial Competency Assessment** | | |
| 1. Employee must read the procedure. 2. Employee will observe trainer performing the procedure. 3. Employee will demonstrate the ability to perform procedure, record results and document corrective action after instruction by the trainer. | | | | | 1. Direct observation. | | |
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| **Historical Record** |  |  | |  | | |  | |
|  | **Version** | **Written/Revised by:** | | **Effective Date:** | | | **Summary of Revisions** | |
| 1 | Pat Ackerman | | 07/31/1985 | | | Initial Version | |
| 1.1 | Pat Ackerman | | 12/22/1993 | | |  | |
| 1.2 | Pat Ackerman | | 12/26/1995 | | |  | |
|  | 1.3 | EM | | 07/18/2007 | | | Modified entire document: added dilution protocol, updated exception list, references, technical support contacts. | |  |  |
| 1.4 | Becky Carlson | | 05/20/2012 | | | Added Shipping instructions for St Paul organisms. Added set up instructions for agar slant cultures. | |
| 1.5 | Becky Carlson | | 12/20/2012 | | | Removed Shipping instructions; agar slant culture instructions. Added procedure for St Paul QC to be done in Mpls and record keeping information. | |
|  | 1.6 | Tina Gronquist | | 7/28/2014 | | | Updated into online format | |
|  | 2 | Becky Carlson | | 4/4/2015 | | | Re-numbered from MC 802 | |
|  | 3 | Becky Carlson | | 7/17/2016 | | | Added reference to IQCP for Exempt Media | |
|  | 3 | Susan DeMeyere | | 6/30/2017 | | | Added manufacture information regarding expiration dates. | |
|  | 4 | Susan DeMeyere | | 2/6/2018 | | | Fix hyperlink for St Paul Media QC form | |
|  | 5 | Susan DeMeyere | | 4/28/2022 | | | Added information of non-exempt media, visual examination | |
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