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QUALITY MANAGEMENT AND QUALITY CONTROL			
GENERAL ISSUES			
IMM.30000 Instrument Maintenance Evaluation	There is documentation of monthly evaluation of the maintenance and function of all instruments, including documentation of corrective action taken when values for instrument function, temperature, etc. exceed defined tolerance limits.	Phase II	N/A
IMM.30100 Numeric QC Data	For numeric QC data, statistics (such as S.D. and C.V.) are calculated monthly to define analytic precision. Evidence of Compliance: ✓ Written procedure for monitoring analytic imprecision including statistical analysis of data AND ✓ QC records showing monthly monitoring for imprecision	Phase II	N/A
IMM.30120 Precision Statistics Action	The laboratory has an action protocol when data from precision statistics change significantly from previous data. Evidence of Compliance: ✓ Records of investigation and corrective actions taken	Phase I	N/A
SPECIMEN COLLECTION AND HANDLING			
IMM.31300 Specimen Identity/Integrity	Procedures are adequate to verify sample identity and integrity (includes capillary specimens, aliquots and dilutions). Evidence of Compliance: ✓ Patient collection and processing records	Phase II	?
IMM.31400 Specimen Rejection Criteria	There are documented criteria for the rejection of unacceptable specimens and the special handling of sub-optimal specimens. Evidence of Compliance: ✓ Records of rejected specimens	Phase II	Records in CRM
RESULTS REPORTING			
IMM.32000 Reference Intervals Established	Reference intervals (normal values) are established or verified by the laboratory for the population being tested.	Phase II	N/A
IMM.32050 Reference Intervals	As appropriate, all patient results are reported with accompanying reference (normal) intervals or interpretations.	Phase II	N/A

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CALIBRATION AND STANDARDS			
IMM.33337 Calibration, Calibration/Verification - Waived Tests	For waived tests, testing personnel follow manufacturer instructions for calibration, calibration verification, and related functions. Evidence of Compliance: ✓ Written procedure consistent with the manufacturer's instructions for each waived test AND ✓ Records for calibration/calibration verification/related functions documented as required by the manufacturer	Phase II	N/A
IMM.33374 Calibration and Controls	Calibration procedures for each test system are adequate, and appropriate controls are used in each run or batch of samples.	Phase II	N/A
IMM.33448 Calibration Materials	High quality materials with test system and matrix-appropriate target values are used for calibration and calibration verification whenever possible. Evidence of Compliance: ✓ Written procedure defining the use of appropriate calibration/calibration verification materials	Phase II	N/A
IMM.33522 Calibration Material Labeling	All calibration materials are properly labeled as to content, calibration values, date placed in service, and expiration date (if applicable). Evidence of Compliance: ✓ Written procedure defining elements required for labeling of calibration material	Phase II	N/A
IMM.33670 Calibration/Calibration Verification Criteria	Criteria are established for frequency of recalibration or calibration verification, and the acceptability of results. Evidence of Compliance: ✓ Written procedure defining the method, frequency and limits of acceptability of calibration verification for each instrument/test system AND ✓ Records of calibration verification documented at defined frequency	Phase II	N/A
IMM.33744 Recalibration	The test system is recalibrated when calibration verification fails to meet the established criteria of the laboratory. Evidence of Compliance: ✓ Written procedure defining criteria for recalibration AND ✓ Records of recalibration, if calibration or calibration verification has failed	Phase II	N/A

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IMM.33818 AMR Verification	Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials which, at a minimum, include the low, mid and high range of the AMR, appropriate acceptance criteria are defined, and the process is documented. Evidence of Compliance: ✓ Written procedure for AMR validation/revalidation defining the types of materials used, frequency and acceptability criteria	Phase II	N/A
IMM.33900 Diluted or Concentrated Samples	If a result is less than or greater than the AMR, a numeric result is not reported unless the sample is processed by dilution, a mixing procedure or concentration so that the processed result falls within the AMR.	Phase II	N/A
IMM.33905 Qualitative Cut-Off	For qualitative tests that use a cut-off value to distinguish positive from negative, the cut-off value is established initially, and verified every 6 months thereafter. Evidence of Compliance: ✓ Written procedure for initial establishment and verification of the cut-off value AND ✓ Records of initial establishment and verification of cut-off value documented at defined frequency	Phase II	N/A - does not apply to FDA-approved IVD assays
IMM.33910 Maximum Dilution/Concentration	For analytes that may have results falling outside the limits of the AMR, the laboratory procedure specifies the maximum concentration or dilution that may be performed to obtain a reportable numeric result. Evidence of Compliance: ✓ Patient results or worksheets	Phase II	N/A
WAIVED TESTS			
IMM.33930 Documented QC Results - Waived Tests	Control results are documented for quantitative and qualitative tests, as applicable.	Phase II	N/A
IMM.33940 QC Corrective Action - Waived Tests	There is evidence of corrective action when control results exceed defined acceptability limits.	Phase II	N/A
IMM.33950 QC Confirmation of Acceptability - Waived	The results of controls are verified for acceptability before reporting results. Evidence of Compliance: ✓ Records showing verification of acceptability of QC	Phase II	N/A

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NONWAIVED TESTS			
IMM.34120 Daily QC - Nonwaived Tests	Controls are run daily for quantitative and qualitative tests. Evidence of Compliance: ✓ Records of QC results including external and electronic/procedural/built-in control systems AND ✓ Records documenting in-house validation of electronic/procedural/built-in control systems, if used	Phase II	Refer to the Immunology Test Log for internal control documentation. See external control QC results in LIS under function MQCR
IMM.34140 QC Range Verification	For quantitative tests, a valid acceptable range has been established or verified for each lot of control material. Evidence of Compliance: ✓ Written procedure defining methods used to establish or verify control ranges AND	Phase II	N/A
IMM.34142 Calibrators and Controls	If the laboratory prepares calibrators and controls in-house, these materials are prepared separately. Evidence of Compliance: ✓ Written procedure defining criteria for in-house preparation of calibrators and controls	Phase II	N/A
IMM.34145 Calibrators as Controls	If a calibrator obtained from an outside supplier is used as a control, it is a different lot number from that used to calibrate the method. Evidence of Compliance: ✓ Written procedure defining the criteria for the use of calibrators as controls AND ✓ QC/calibrator records	Phase I	N/A
IMM.34150 Control Labeling	Controls are properly labeled as to content, lot number, date of preparation and expiration date. Evidence of Compliance: ✓ Written policy defining elements required for control labeling	Phase II	Added to Mono procedure. HIV controls are commercial products.
IMM.34170 Weakly Reactive Controls	Reactive, weakly reactive and nonreactive controls are all used in test systems where results are reported in that fashion. Evidence of Compliance: ✓ QC results	Phase II	N/A

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IMM.34190 Documented QC	There are records to reflect the results of all control procedures.	Phase II	Refer to the Immunology Test Log for internal control documentation. See external control QC results in LIS under function MQCR
IMM.34250 QC Corrective Action	There is documentation of corrective action taken when results of controls exceed defined acceptability limits.	Phase II	Corrective action would be documented in LIS and can be viewed under function MQCR
IMM.34270 QC Handling	Control specimens are tested in the same manner and by the same personnel as patient samples. Evidence of Compliance: ✓ Records reflecting that QC is run by the same personnel performing patient testing	Phase II	See employee numbers of those entering results in LIS (MQCR)
IMM.34290 QC Confirmation of Acceptability	The results of controls are reviewed for acceptability before reporting results. Evidence of Compliance: ✓ Written policy/procedure stating that controls are reviewed and acceptable prior to reporting patient results AND ✓ Evidence of corrective action taken when QC results are not acceptable	Phase II	See Mono and HIV procedures for written policy. Corrective action would be documented in LIS.
IMM.34362 Monthly QC Review	Quality control data are reviewed and assessed at least monthly by the laboratory director or designee. Evidence of Compliance: ✓ Records of QC review with documented follow-up for outliers, trends or omissions	Phase II	Refer to the monthly QC reports reviewed and initialled by the supervisor.
IMM.34450 Fluorescent/Enzyme Antibody Stain QC	Positive and negative controls are included with each patient run for all fluorescent or enzyme antibody stains.	Phase II	N/A
IMM.34475 Validation of Accuracy	If the laboratory performs test procedures for which calibration or control materials are not commercially available, guidelines have been established to validate the initial calibrators and controls, and to verify the reliability of patient test results.	Phase II	N/A
IMM.34500 Comparability of Instrument/Method	If the laboratory uses more than one instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for correlation of results.	Phase II	N/A

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INSTRUMENTS AND EQUIPMENT			
IMM.34550 Thermometric Standard Device	An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards) is available. Evidence of Compliance: ✓ Thermometer certificate of accuracy	Phase II	Certificate kept in Chemistry
IMM.35000 Non-Certified Thermometers	All non-certified thermometers in use in the laboratory are checked against an appropriate thermometric standard device before being placed in service. Evidence of Compliance: ✓ Written procedure defining criteria for verification of non-certified thermometers AND ✓ Records of verification prior to being placed in service	Phase II	Refer to the Non Certified Thermometer check procedure located in Lab General under Quality Management. Records are stored in the Micro Reagent Prep Room.
IMM.35050 Temperature Checks	The temperature of water baths and/or heat blocks, refrigerators and other temperature-dependent equipment is checked and recorded daily.	Phase II	Refer to LIS under function MQCR for specific temp QC records.
IMM.35070 Incubator QC	On days of use, the incubator is monitored for temperature, CO2 concentration and humidity as defined by the procedure manual.	Phase II	N/A
IMM.35075 Serologic Centrifuge Checks	Mechanical timers on serologic centrifuges, and the speed of the centrifuge, are checked for accuracy every 6 months. Evidence of Compliance: ✓ Records of serologic centrifuge checks documented at defined frequency	Phase I	Records of centrifuge checks are maintained by clinical engineering.
IMM.35100 Function Checks	Appropriate function checks are performed for all instruments and equipment prior to testing patient samples.	Phase II	No instruments are used for HIV or Mono tests.
IMM.35150 Routine Maintenance Schedule	All instruments and equipment are on a routine maintenance schedule.	Phase II	No instruments are used for HIV or Mono tests.
IMM.35200 Instrument/Equipment Service Records	Instrument and equipment maintenance, service and repair records (or copies) are promptly available to, and usable by, the technical staff operating the equipment.	Phase II	No instruments are used for HIV or Mono tests.
IMM.35216 Pipette Accuracy	Glass volumetric pipettes are of certified accuracy (Class A); or they are checked by gravimetric, colorimetric, or some other validation procedure before initial use.	Phase II	N/A
IMM.35232 Pipette Accuracy	Non-class A pipettes that are used for quantitative dispensing of material are checked for accuracy and reproducibility at specified intervals, and results documented.	Phase II	N/A

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IMM.35250 Automatic Pipette Accuracy	Automatic and adjustable pipetting devices are checked at least annually for accuracy and reproducibility, and results recorded. Evidence of Compliance: ✓ Written procedure detailing method for checking the accuracy and reproducibility of automatic pipettes AND ✓ Records of initial and periodic pipette verification documented at defined frequency	Phase II	Refer to pipette calibration records located on the G drive (accessible by director, supervisor and technical specialist).
IMM.35275 Concentration Techniques	Concentration techniques are verified. Evidence of Compliance: ✓ Written procedure for verifying the accuracy of concentration techniques AND ✓ Records of concentration technique verification documented at defined frequency	Phase I	N/A for Mono and HIV tests
IMM.35603 Pipette Carryover	The laboratory has evaluated its automatic pipetting systems for carryover.	Phase II	No automatic pipettes in use.
IMM.35957 Glassware Accuracy	Glass volumetric flasks are of certified accuracy (Class A, National Institute of Standards and Technology (NIST) standard or equivalent), or if non-certified volumetric glassware is used, all items are checked for accuracy of calibration before initial use.	Phase II	N/A for Mono and HIV tests
ANALYTIC BALANCES			
IMM.36664 Balance Maintenance	Balances are cleaned, serviced and checked at least annually only by qualified service personnel (i.e. service contract or as needed).	Phase I	N/A for Mono and HIV tests
IMM.37371 Balance Mounting	Analytic balances are mounted such that vibrations do not interfere with readings.	Phase I	N/A for Mono and HIV tests
IMM.38078 Standard Weights	Standard weights of the appropriate ANSI/ASTM Class are available and used for checking accuracy.	Phase II	N/A for Mono and HIV tests
IMM.38785 Balance Accuracy	Results of periodic accuracy checks are recorded.	Phase II	N/A for Mono and HIV tests
IMM.39492 Weight Maintenance	Weights are well-maintained (clean, in a covered container, not corroded) and appropriate lifting or handling devices are available.	Phase II	N/A for Mono and HIV tests
Direct Antigen Testing			
IMM.41810 Group A Streptococcus Direct Antigen Detection	If group A Streptococcus direct antigen testing is performed, additional confirmatory testing is performed on negative samples.	Phase I	See Rapid GAS Procedure.

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IMM.41840 Cryptococcal Antigen	If cryptococcal antigen-detection methods are used on CSF, back-up cultures are performed on positive CSF specimens submitted for diagnosis.	Phase II	See Microbiology checklist
IMM.41850 Direct Antigen Test QC	For nonwaived direct antigen tests on patient specimens that DO include internal controls, a positive and negative external control are tested and documented with each new kit lot number or shipment, and as frequently as recommended by the manufacturer, or every 30 days (whichever is more frequent).	Phase II	See Microbiology checklist
IMM.41860 Direct Antigen Test QC	For nonwaived direct antigen tests on patient specimens that do NOT include internal controls, a positive and negative control are tested and documented each day of patient testing.	Phase II	See Microbiology checklist
PERSONNEL			
IMM.50000 Bench Testing Supervision	The person in charge of the bench testing/section supervisor in immunology and syphilis serology has education equivalent to an associate's degree (or beyond) in a chemical, physical or biological science or medical technology and at least 4 years experience (one of which is in immunology and syphilis serology) under a qualified section director. Evidence of Compliance: ✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field	Phase II	Refer to supervisor records.