

D.21 ANCILLARY TESTING QUALITY MANAGEMENT POLICY

VAWNY HEALTHCARE SYSTEM
PATHOLOGY AND LABORATORY MEDICINE
ANCILLARY TESTING

ANCILLARY TESTING QUALITY MANAGEMENT POLICY

I. PURPOSE

To monitor and evaluate the quality of the point-of-care testing processes, identify and correct problems and assure accurate, reliable and prompt reporting of patient results. All testing below may not be performed at all locations. Sites should contact the Ancillary Testing Coordinator with any questions regarding what testing is approved for their area.

II. INSTURMENTS

A. INFORM II WHOLE BLOOD GLUCOSE TESTING

1. PERSONNEL

- Testing may be performed by Physicians, Physician Assistants, Nurse Practitioners, Registered Nurses, Licensed Practical Nurses, Respiratory Therapists or other qualified personnel who have been properly trained.
- Initial Competency is established through orientation training and is documented through Ancillary Testing. This orientation training will include a review of policies as well as technical procedures. A list of trained personnel is maintained by Ancillary Testing.
- Ongoing competency is accomplished by the correct performance of two levels of quality control material or proficiency testing and completion of an annual competency assessment quiz. Documentation is maintained by Ancillary Testing.

2. TESTING PROCEDURE

- All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified verbally by the patient, from the patient's wrist ID or from the patient's Veterans Identification Card. The patient is identified in the Accu-Chek Inform II by scanning or manually entering the patient's nine-digit social security number. ID numbers are manually entered only if there is no wrist band or VIC card.
- The person performing the test is identified by scanning or manually entering their Operator ID Number into the Inform. The patient identification, the testing personnel identification, and the patient results are "downloaded" into the RALS computer interface system. Results with invalid patient ID's are rejected.
- All valid patient results are entered into the laboratory package of the VISTA hospital computer system by the RALS computer system to become a part of the patient's permanent record.
- Notification of all critical values is documented in the patient's record using the approved "Critical Glucometer Value Template".
- All patient results flagged by the RALS system are reviewed by the Ancillary Testing Coordinator, i.e. results with invalid operator or patient ID's, "testing error" comments, results without a valid ordering location or provider, results outside the AMR, etc.
- If there is a discrepancy/problem noted, the testing personnel and the nurse manager of the area are contacted via e-mail to determine what happened so that a decision on whether to mark a result for "upload" or "do not upload" can be made. Documentation is provided and entered into RALS. Corrective action is taken as needed.
- A quality assurance excel spread sheet is used to track problems.
- A quarterly QA report is sent to all nurse managers

3. QUALITY CONTROL

- Control solution monitors the ongoing performance of the entire analytic process. Two levels of control solution must be run every 24 hours. (If patient testing is not performed every day, the controls may be performed only when patient testing is performed.)
- The controls are tested by the same personnel that perform patient testing.
- Quality Control ranges are stored in the Accu-Chek Inform II and the operator is alerted if the controls are not acceptable.
- The Accu-Chek Inform II Whole Blood Glucose System is programmed for “True QC Lockout”. If the control solutions are not within acceptable range, the Inform meter will not allow patient testing. Any corrective action taken must be documented by the use of comment codes.
- All QC data is reviewed at least monthly by Ancillary Testing and maintained in the laboratory for at least two years.
- The tolerance limits of each lot number of glucose control solution are verified by the Ancillary Testing before the lot number is placed in use. This is accomplished by running repetitive testing on each new lot of control solution.

4. CALIBRATION

- The Accu-Chek Inform II is calibrated by the use of the Key Chip that is found in each box of the Inform II strips. This code can only be put in by the Ancillary Testing Coordinator. New lots of strips will be evaluated by the ATC before that strip lot is put into use.
- Calibration is verified by running Levels 1 & 2 of the glucose control solutions.

5. STRIP VALIDATION

- New lot numbers of Inform II Strips are checked by Ancillary Testing for acceptability. This is accomplished by:
 - Performance of new strip lots may be verified by performing Linearity Testing in duplicate.
- Verifications are performed before the lot number is distributed to testing sites. Documentation of these reagent checks is maintained by Ancillary Testing.

6. INSTRUMENT VALIDATION AND MAINTENANCE

- Before an Accu-Chek Inform II is placed in service, a linearity test is performed on the meter. A minimum of five levels of linearity solutions are run in duplicate.
- Linearity testing is used to verify the calibration and reportable ranges of the Accu-Chek Inform II system.
- Linearity testing may also be performed as part of troubleshooting. Documentation of linearity testing is maintained by Ancillary Testing.
- Correlation (method comparison) of Accu-Chek Inform II glucose results with laboratory glucose results is accomplished by randomly selecting and comparing patients who have had an Accu-Chek Inform II glucose test and a laboratory glucose test performed within 30 minutes of each other. This documentation is maintained in the laboratory. Performed once every 6 months.
- The only regular maintenance required is disinfection of the meter between patient uses. Any other maintenance is recorded in RALS by Ancillary Testing staff.

B. i-STAT

• PERSONNEL

- Testing may be performed by Physicians, Physician Assistants, Nurse Practitioners, Registered Nurses, Licensed Practical Nurses, Respiratory Therapists or other qualified personnel who have been trained by Ancillary Testing.

- Initial Competency is established through orientation training and documented through Ancillary Testing. This orientation training will include a review of policies and technical procedures. The trainees will complete a post-orientation self-knowledge test. A list of trained personnel is maintained by the laboratory.
- For non-waived i-STAT testing, training will also include a “hands on” performance of patient testing that is observed by the trainer. This direct observation may be performed by Ancillary Testing staff.
- Ongoing competency is accomplished by analyzing operator error codes monthly, participation in proficiency testing and completion of a quiz. Documentation is maintained by the Ancillary Testing.
- Ongoing competency for non-waived i-STAT testing will also include a direct observation of routine patient testing. This direct observation may be by Ancillary Testing staff.
- **TESTING PROCEDURE**
 - All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified verbally by the patient, from the patient’s wrist ID or from the patient's Veterans Identification Card. The patient is identified in i-STAT by scanning or manually entering the patient’s nine-digit social security number. ID numbers are manually entered only if there is no wrist band or VIC card.
 - The person performing the test is identified by scanning or manually entering their Operator ID Number into i-STAT.
 - All valid patient results are entered into the laboratory package of the VISTA hospital computer system by the RALS computer system to become a part of the patient’s permanent record
- **QUALITY CONTROL**
 - Internal electronic quality control is automatically performed every 8 hours of use. No operator intervention is necessary. A FAILED electronic QC will lock the i-STAT’s patient testing option.
 - When a new lot or shipment of cartridges is received, all appropriate levels of aqueous controls are tested. Two levels of liquid controls will be run at least once per month.
 - Aqueous control ranges are stored in the i-STAT analyzer and the operator will be alerted as to whether the control passed or failed.
 - Controls are not used past their expiration date and always handled according to the manufacturer’s instructions.
 - All QC data is reviewed at least monthly by Ancillary Testing. Records of all QC data and review are maintained by the Ancillary Testing Coordinator.
- **CALIBRATION VERIFICATION**
 - Calibration of the I-STAT 1 system is automatically performed as part of the test cycle on each cartridge and does not require any action by the operator. Calibration verification is performed by initially running all levels of linearity materials and appropriate levels at 6 month intervals. Performance of at least 3 levels of linearity material that cover the analytical measurement range for each analyte are run. I-Stat calibrators are used.
- **INSTRUMENT VALIDATION AND MAINTENANCE**
 - Before an i-STAT is place in service, appropriate validation studies will be performed.
 - Appropriate liquid controls for all cartridges which will be used on the analyzer as well as the electronic simulator are tested before the i-STAT is placed into service.
 - Correlation (method comparison) of i-STAT results with laboratory results is performed every 6 months. This documentation is maintained by Ancillary Testing.
 - The only regular maintenance required is disinfection of the analyzer between patient uses.

C. OXIMETRY (AVOXIMETER)

1. PERSONNEL

- Testing may be performed by nurses and techs in the Cardiac Catheterization Lab who have been trained by the Ancillary Testing Coordinator.
- Cardiac Cath Lab staff members undergo initial training and competency and then annually thereafter. Documentation is maintained in the Ancillary competency binder.

2. TESTING PROCEDURE

- All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified from the patient's wrist ID or from the patient's Veterans Identification Card before beginning the case/Cath procedure.
- Results are recorded in the Cardiac Catheterization report. The report scanned into VISTA imaging and is available in the permanent patient record.

3. QUALITY CONTROL

- Two levels of control filters are run each day that the Avoximeter is used.
- Two levels of liquid control are to be run weekly to verify calibration and any time the daily QC filter results are unacceptable.
- All control results are verified to be acceptable according to the manufacturer's ranges and recorded in the control log. If any results are not in range, corrective action is documented in the control log.

4. CALIBRATION

- Calibration is not routinely required, and if so, it must be performed by the manufacturer.

5. INSTRUMENT VALIDATION AND MAINTENANCE

- Cuvette Validation: Enter path length and run Liquid QC
- Before an Avoximeter is placed into service, Calibration Verification material is tested to validate the analyzer measurement range.
- Linearity must be performed every 6 months.
- Correlation (method comparison) of Avoximeter results with laboratory results is performed every 6 months. This documentation is maintained by Ancillary Testing
- The only regular maintenance required is cleaning of the analyzer as needed.

D. COAGUCHECK XS PLUS WHOLE BLOOD INR TESTING

1. PERSONNEL

- Testing may be performed by Physicians, Registered Nurses, Licensed Practical Nurses, or other qualified personnel who have been properly trained.
- Initial Competency is established through orientation training and is documented through Ancillary Testing. This orientation training will include a review of policies as well as technical procedures. A list of trained personnel is maintained by Ancillary Testing.
- Ongoing competency is accomplished by the correct performance of two levels of quality control material, proficiency testing, or patient testing and completion of an annual competency assessment quiz. Documentation is maintained by Ancillary Testing.

2. TESTING PROCEDURE

- All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified verbally by the patient, from the patient's wrist ID or from the patient's Veterans Identification Card. The patient is identified in the meter by manually entering the patient's nine-digit social security number.

- The person performing the test is identified by manually entering their Operator ID Number into the Inform. The patient identification, the testing personnel identification, and the patient results are “downloaded” into the RALS computer interface system. Results with invalid patient ID's are rejected.
- All valid patient results are entered into the laboratory package of the VISTA hospital computer system by the RALS computer system to become a part of the patient's permanent record.
- Notification of all critical values is documented in the patient's record using the approved “Critical Fingerstick INR Value Template”.
- All patient results flagged by the RALS system are reviewed by the Ancillary Testing Coordinator.
- If there is a discrepancy/problem noted, the testing personnel and the nurse manager of the area are contacted via e-mail to determine what happened so that a decision on whether to mark a result for “upload” or “do not upload” can be made. Documentation is provided and entered into RALS. Corrective action is taken as needed.
- A quality assurance excel spread sheet is used to track problems.
- A quarterly QA report is sent to all nurse managers

3. QUALITY CONTROL

- Control solutions monitor the ongoing performance of the entire analytic process. Two levels of control solution must be run at least monthly.
- The controls are tested by the same personnel that perform patient testing.
- Quality Control ranges are stored in the meter and the operator is alerted if the controls are not acceptable.
- The CoaguChek XS Plus is programmed for “True QC Lockout”. If the control solutions are not within acceptable range, the meter will not allow patient testing. Any corrective action taken must be documented by the use of comment codes.
- All QC data is reviewed at least monthly by Ancillary Testing and maintained in the laboratory for at least two years.
- The tolerance limits of each lot number of control solution are verified by the Ancillary Testing before the lot number is placed in use. This is accomplished by running testing on each new lot of control solution.

4. CALIBRATION

- The CoaguChek XS Plus is calibrated by the use of the Key Chip that is found in each box of strips. New lots of strips will be evaluated by the ATC before that strip lot is put into use.
- Calibration is verified by running Levels 1 & 2 of control solution.

5. STRIP VALIDATION

- New lot numbers of strips are checked by Ancillary Testing for acceptability. This is accomplished by performing Levels 1 & 2 of control solution. Verifications are performed before the lot number is distributed to testing sites. Documentation of these reagent checks is maintained by Ancillary Testing.

6. INSTRUMENT VALIDATION AND MAINTENANCE

- Before a CoaguChek XS Plus is placed in service a minimum of 2 replicates of Levels 1 & 2 of control solution must be tested.
- Correlation (method comparison) of INR results with laboratory INR results is accomplished by randomly selecting and comparing patients who have had a fingerstick INR test and a laboratory INR test performed within 30 minutes of each other. This documentation is maintained in the laboratory. Evaluated once every 6 months, result are collected randomly.
- Regular maintenance required is disinfection of the meter between patient uses and monthly cleaning of the strip slot guide. Any other maintenance is recorded in RALS by Ancillary Testing staff.

E. URINE HCG TESTING (QUALITATIVE)

1. PERSONNEL

- Testing may be performed by Registered Nurses, Licensed Practical Nurses and Phlebotomist who have been trained.
- Competency is established through training and documented through Ancillary Testing. This training will include a review and instruction on HCG testing procedure, order and specimen requirements, quality control requirements and proper reporting of results.
- Ongoing competency is accomplished by the correct performance of two levels of quality control material, proficiency testing, or patient testing and completion of an annual competency assessment quiz. Documentation is maintained by Ancillary Testing

2. TESTING PROCEDURE

- All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified verbally by the patient, from the patient's wrist ID or from the patient's Veterans Identification Card.
- Perform testing according to manufacturer's instructions.
- All valid patient results are entered into the laboratory package of the VISTA hospital computer system to become a part of the patient's permanent record.

3. QUALITY CONTROL

- The internal control built into each test cartridge must develop appropriately with each test or the test is not reportable and must be repeated. Built in/Internal control results are recorded along with the patient result.
- Two levels of external controls shall be performed, upon new lot receipt, and at minimum once per month or if deviation in storage temperature is noted.
- All QC data is reviewed at least monthly by Ancillary Testing and maintained in the laboratory for at least two years.

F. BUPRENORPHINE

1. PERSONNEL

- Testing may be performed by Registered Nurses, Licensed Practical Nurses who have been trained.
- Competency is established through training and documented through Ancillary Testing. This training will include a review and instruction on the testing procedure, order and specimen requirements, quality control requirements and proper reporting of results.
- Ongoing competency is accomplished by the correct performance of two levels of quality control material, proficiency testing, or patient testing and completion of an annual competency assessment quiz. Documentation is maintained by Ancillary Testing

2. TESTING PROCEDURE

- All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified verbally by the patient, from the patient's wrist ID or from the patient's Veterans Identification Card.

- Perform testing according to manufacturer's instructions.
- All valid patient results are entered into the laboratory package of the VISTA hospital computer system to become a part of the patient's permanent record.

3. QUALITY CONTROL

- The internal control built into each test cartridge must develop appropriately with each test or the test is not reportable and must be repeated. Built in/Internal control results are recorded along with the patient result.
- Two levels of external controls shall be performed, upon new lot receipt, and at minimum once per month or if deviation in storage temperature is noted.
- All QC data is reviewed at least monthly by Ancillary Testing and maintained in the laboratory for at least two years.

G. PPM (KOH Prep, Oil emersion and Vaginal Wet prep)

1. PERSONNEL

- Testing may be performed by Providers and Nurse Practitioners.
- Competency is established through training and documented through Ancillary Testing. This training will include a review and instruction on the testing procedure, order and specimen requirements, quality control requirements and proper reporting of results.
- Ongoing competency is completed yearly. Documentation is maintained by Ancillary Testing

2. TESTING PROCEDURE

- All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified verbally by the patient, from the patient's wrist ID or from the patient's Veterans Identification Card.
- Perform testing according to manufacturer's instructions.
- All valid patient results are entered into a CPRS progress note and become a part of the patient's permanent record.

H. DCA VANTAGE A1C

1. PERSONNEL

- Testing may be performed by Registered Nurses, Licensed Practical Nurses, or other qualified personnel who have been properly trained.
- Initial Competency is established through orientation training and is documented through Ancillary Testing. This orientation training will include a review of policies as well as technical procedures. A list of trained personnel is maintained by Ancillary Testing.
- Ongoing competency is accomplished by the correct performance of two levels of quality control material, proficiency testing, or patient testing and completion of an annual competency assessment quiz. Documentation is maintained by Ancillary Testing.

2. TESTING PROCEDURE

- All samples collected for analysis are obtained from patients whose patient's name and identification number have been verified verbally by the patient, from the patient's wrist ID or from the patient's Veterans Identification Card. The patient is identified in the meter by manually entering the patient's nine-digit social security number.
- The person performing the test is identified by manually entering their Operator ID Number into the analyzer
- Perform testing according to manufacturer's instructions.

- All valid patient results are entered into the laboratory package of the VISTA hospital computer system to become a part of the patient's permanent record.

3. QUALITY CONTROL

- These control solutions to monitor the ongoing performance of the entire analytic process. Two levels of control solution must be run at least monthly.
- The controls are tested by the same personnel that perform patient testing.
- Quality Control ranges are stored in the meter and the operator is alerted if the controls are not acceptable.
- The CoaguChek XS Plus is programmed for "True QC Lockout". If the control solutions are not within acceptable range, the meter will not allow patient testing. Any corrective action taken must be documented by the use of comment codes.
- All QC data is reviewed at least monthly by Ancillary Testing and maintained in the laboratory for at least two years.
- The tolerance limits of each lot number of control solution are verified by the Ancillary Testing before the lot number is placed in use. This is accomplished by running testing on each new lot of control solution.

4. CALIBRATION

- The CoaguChek XS Plus is calibrated by the use of the Key Chip that is found in each box of strips. New lots of strips will be evaluated by the ATC before that strip lot is put into use.
- Calibration is verified by running Levels 1 & 2 of control solution.

5. STRIP VALIDATION

- New lot numbers of strips are checked by Ancillary Testing for acceptability. This is accomplished by performing Levels 1 & 2 of control solution.
- Verifications are performed before the lot number is distributed to testing sites. Documentation of these reagent checks is maintained by Ancillary Testing.

6. INSTRUMENT VALIDATION AND MAINTENANCE

- Before a CoaguChek XS Plus is placed in service a minimum of 2 replicates of Levels 1 & 2 of control solution must be tested.
- Correlation (method comparison) of INR results with laboratory INR results is accomplished by randomly selecting and comparing patients who have had a fingerstick INR test and a laboratory INR test performed within 30 minutes of each other. This documentation is maintained in the laboratory. Evaluated once every 6 months, result are collected randomly.
- Regular maintenance required is disinfection of the meter between patient uses and monthly cleaning of the strip slot guide. Any other maintenance is recorded in RALS by Ancillary Testing staff.

III. PROFICIENCY TESTING

- A. All Ancillary Testing sites participate in CAP Proficiency Testing
- B. Peer group based accuracy of instruments is assessed by proficiency testing. An appropriate proficiency survey from CAP is performed on each instrument.
- C. PT samples are processed as closely as possible to the same manner as patient samples are processed by the personnel that routinely perform the patient testing.
- D. This testing is rotated among the personnel that perform the patient testing and is performed on all instruments that are being used for patient testing.
- E. Laboratory Director or designee and the Ancillary Testing Coordinator review all CAP Survey Evaluations. All out of range results are investigated and appropriate corrective actions are taken.

- F. After the deadline for submission of CAP results has passed, instrument to instrument comparisons are performed by analyzing CAP Survey sample results. All documentation is maintained by Ancillary Testing
- G. Documentation is maintained by Ancillary Testing for two years on these processes.

IV. REFERENCE:

- A. CAP checklist POC 8/17/2016
- B. Manufactures Instrument manuals and package inserts
- C. VHA Waived Testing Regulations Guideline, March 7, 2013
- D. VHA Handbook 1106.01, January 29, 2016
- E. CM113-10 Ancillary Testing Policy

V. ATTACHMENTS:

- ### A. Instrument and Reagent Lot Validation

VI. HISTORICAL RECORD

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ATTACHMENT: A Instrument and Reagent Lot Validation

The following chart covers the requirements for instrument and reagent validation for each type of analyzer/cartridge used in point of care testing. It also includes which analyzers need calibration verification and patient crossovers performed at the required intervals, initially and at 6 month

INSTRUMENT	INITIAL LINEARITY	6 MONTH LINEARITY	INITIAL PATIENT CROSSOVERS	6 MONTH PATIENT CROSSOVERS	QC PERFORMED	REAGENT LOT VALIDATION	QC LOT VALIDATION
WAIVED TESTS							
Glucometers QC, linearity from Roche	X		X	X (10% of meters)	2 Levels Every 24hrs	QC and linearity in duplicate	New QC run on old lot
DCA Vantage QC from RNA Medical			X	X	2 Levels Monthly	Liquid QC	New QC run on old lot
Buprenorphine QC from Detectabuse					Internal Cartridge QC / 2 Levels Monthly	Liquid QC	New QC run on old lot
Urine Pregnancy QC from Sure-View					Internal Cartridge QC / 2 Levels Monthly	Liquid QC	New QC run on old lot
CoaguChek QC form Roche			X	HBPC Only (10% of meters)	Two levels on each Strip/ 2 Levels Monthly	Liquid QC	New QC run on old lot
I-STAT QC I-STAT Tri Control Crea	X		X	X	EQC/ 2 Levels Monthly	Liquid QC	New QC run on old lot
NON WAIVED TESTS							
I-STAT EG7+ QC I-Stat TRIcontrols and calibrators	X	X	X	X	*EQC/ 2 Levels At least Every 31 Days	Liquid QC	New QC run on old lot
I-STAT ACT-K QC from I-Stat	N/A	N/A	X CAP samples used	X CAP samples used	*EQC/ 2 Levels At least Every 31 Days	Liquid QC	New QC run on old lot
Avoximeter QC and Cal/ver from RNA Medical	X	X	X	X	*Daily Paddles Weekly Liquid QC	N/A	New QC run on old lot

Refer to the individual Device procedure, IQCP, and Manufactures Procedure for more details

*IQCP N/A = not applicable X= performed