Chemistry

Requirements for good laboratory practice and COLA Laboratory Accreditation programs are underlined.

SPECIMEN COLLECTION AND HANDLING

The first step in performing a chemistry test is the collection of the appropriate specimen from the patient. Some manufacturers provide a reference chart with their instrument listing what specimens are necessary for each test. The procedure manual for the instrument, or the laboratory's specimen collection procedure, should contain additional information on specimen collection such as which anticoagulant or preservatives are suitable for each test procedure.

Follow the instructions in the reference laboratory's manual on specimen collection and handling if a specimen is being collected to be sent to a reference laboratory.

Once the specimen has been collected, follow the precise handling conditions as required by the test procedure. For example, carefully perform centrifuging and separating serum or plasma from whole blood to avoid damage to the specimen. It is also crucial to correctly label each specimen with a unique identifier immediately after it is collected.

If it is necessary to store the specimen, be sure to do so according to requirements of the test procedure. Freeze, thaw, or refreeze specimens in a manner so that the specimen is not damaged. Appropriately package specimens that must be transported to a reference lab.

All instructions on the collection and handling of chemistry specimens should be documented in the laboratory's procedure manual. The manual should also contain a written policy for the handling of unacceptable or rejected specimens, how to report "panic values," as well as written instructions that can be distributed to patients responsible for collecting their own specimen (i.e., 24-hour urine specimen). Your instrument's operating manual should contain detailed information about specimen collection and handling for your specific test system. Also see LabFacts 1 *Contents of a Procedure Manual*.

PIPETTING

Whether a manual, semi-automated, or automated pipette is used, small mistakes in measuring the volume of a specimen can have serious effects on the test result. Use a pipetting device, such as a pipette bulb, when using a volumetric or serologic pipette. When drawing up and dispensing specimens, hold all pipettes vertically and be careful when wiping the tip that the specimen is not absorbed out of the tip by the wipe. Volumetric, serological, and semi-automated pipettes and diluters should be of certified accuracy, and checked yearly for accuracy. The accuracy of a pipette can be checked by either gravimetric or colorimetric methods. Discard chipped volumetric pipettes. Throw away disposable pipettes after use. Follow the manufacturer's instructions for the proper maintenance of semi-automated or automated pipettes and document this in appropriate maintenance logs. Also see LabFacts 53 *Pipettes and Their Calibration*.

REAGENTS

Label all reagents, including controls and calibrators, with their expiration date, date of initial use, and/or the reconstitution date. Store according to the manufacturer's instructions, and before each use check for contamination, expiration, and correct volume content. Pay special attention to the expiration dates after the reconstitution of a reagent. If reagents are reconstituted in a container other than the one provided by the manufacturer, be sure to correctly label the container. Discard all outdated reagents, controls, or calibrators. Refer to the manufacturer's package inserts for more detailed information on the reagents you use.

CONTROLS

The quality control program for the laboratory should contain written policies and procedures that provide instruction on the use and interpretation of quality control material. For moderate complexity tests, run at least two levels of controls, or follow the manufacturers instructions, whichever is more stringent, and record the control results each day of testing. Some manufacturers require three levels of controls to be run (e.g., Abbott TDx.)

For high complexity tests, use two different concentrations of controls with each patient run. If performing electrophoresis, use one control which contains all fractions to be reported per cell. When performing blood gas analysis, run at least one control every eight hours of each day of testing. If the laboratory is open more than eight hours a day, then run a rotated variety of blood gas control levels, e.g., low, medium, and high, as the single control level.

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Record control values in your quality control logs along with any corrective action taken. Do not report patient test results when control results are out of their acceptable limits. You should have a written procedure in your procedure manual for troubleshooting "out of limit" control results and what to do if your laboratory cannot resolve the problem. Store all quality control records for two years.

The laboratory director or technical consultant should regularly review control data. Levy-Jenning charts are useful for plotting daily quantitative control values and monitoring control values. Refer to the manufacturer's package inserts for more detailed information on the specific controls you use. Also see LabFacts 50/51 *Quality Control Primer*.

CALIBRATION/RECALIBRATION

If your laboratory performs moderate complexity tests, perform calibration, recalibration, or calibration verification at least every six months for each moderate complexity test system.

In addition to twice yearly calibration checks, most manufacturers recommend recalibration whenever a new reagent lot is opened or when maintenance is performed on the instrument. Perform recalibration when quality control results show trends, shifts, out of limit values, and corrective action has not solved the problem.

The manufacturer's reportable range can be used without verification for moderate complexity tests.

If performing high complexity testing, follow acceptable methods for calibration and calibration verification. Recalibrate when:

- Required by the manufacturer.
- New lot numbers are used.
- There is a complete change of reagents.
- The system has a major preventative maintenance workup.
- A critical part is changed.
- The instrument fails calibration verification.
- The quality control material shows shifts, trends, or is out of limits and corrective action has not solved the problem.

In addition for high complexity tests, the calibration procedure must verify the reportable ranges of patient tests by using a minimum value, a mid-point value, and a maximum value. The reportable range for patient tests cannot exceed the highest or lowest value that has been verified for accuracy. Report patient specimens which exceed the reportable range (high or low) as greater than or less than the maximum or minimum calibration value, unless a procedure is used to adjust for specimens beyond the maximum range (e.g., diluting a highly concentrated specimen and multiplying by the dilution factor to bring the specimen into a reportable range).

If applicable, note the stability and expiration date of the calibrator after reconstitution. Also, follow the manufacturer's storage recommendations. Calibrators should be traceable to NIST (National Institute of Standards and Technology) standards, if possible. Document all calibration control values and calibration verification activities.

PREVENTIVE MAINTENANCE

Your instrument's operator's manual should indicate when maintenance is required and at what intervals it must be performed. Record all instrument service or preventive maintenance in your maintenance logs.