

Quality Control for Chemistry Laboratory – Dynacare Kasper Laboratories Procedures

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Abstract

This paper presents the quality control procedure (internal quality control, Westgard rules and external quality control) for chemistry in Dynacare Kasper Medical Laboratory (DKML) from Edmonton, Canada and provide a practical approach to quality control.

Keywords: quality control, clinical chemistry, medical laboratory.

Goals for a quality control program

The first step in establishing a laboratory quality control program is to develop criteria for acceptable laboratory performance. How accurate and precise *should* the laboratory be? How precise and accurate *must* it be?. These considerations include the determination of what constitutes acceptable analytical error based on the use of the test result in clinical care. Control beyond that required for medical purposes can waste time and materials; hence it is important to evaluate whether error reduction improves medical diagnosis, treatment or prognosis.

Several bases exist upon which performance criteria can be formulated. The first is the body of regulatory standards; for example, the

precision and accuracy demanded by Clinical Laboratory Improvement Amendment of 1988 (CLIA'88) regulations. Second are the precision and accuracy that appear to be attainable performance by most laboratories. This information can be obtained by communication with other laboratory professionals or from data derived from proficiency surveys, such as that of the College of American Pathology (CAP). Third and probably most important, it is essential to determine the precision and accuracy required by the clinical staff, the users of data produced by the laboratory. In general, a testing system's analytical error should be much smaller than the allowable error in the regulatory requirements. Otherwise, the laboratory may not meet its regulatory and perhaps medical requirements.

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Medical Decision Limits

For true control of quality it is necessary to evaluate, from the customer's perspective, the performance required for each aspect of the clinical laboratory's operation. The elements of a good quality control program include establishment of analytical accuracy and precision performance criteria based on medical usefulness requirements. Each laboratory should consult the appropriate users or clinicians to obtain their estimate of allowable error based on their particular medical practice. If their suggestions are reasonable and would not place the laboratory conflict with regulatory requirements, the laboratory should try to attain these limits of error. If no information is available about the precision and accuracy targets needed for medical decision making, one can then estimate a theoretical error based on the degree of intra-individual and inter-individual variation for each analyte.

Reference intervals for laboratory tests describe the expected values for carefully selected groups of individuals determined by testing systems that are assumed to be performing appropriately. Increased bias will cause a **shift** in test values and will thus invalidate the medical usefulness of the established reference intervals and may in fact lead to inappropriate patient care.

Meeting Medical Usefulness Criteria by Calculating the Significant Change Limit

The day-to-day medical usefulness of clinical laboratory tests depends on maintaining the accuracy and precision of the testing system. Physicians make many clinical decisions on the basis of the day-to-day differences in patient test values, assuming that the day-to-day accuracy and precision are maintained at the same level from month to month and year to year. Thus the actual accuracy and precision of the measurement procedure directly influence the medical interpretation of these day-to-day

changes in test values. One key element in interpreting the medical usefulness of a test result is an estimate of the magnitude of an analytically significant change in concentration. This estimate is called the *significant change limit (SCL)*.

The significant change limit is a decision – making tool that helps physicians distinguish day-to-day changes in results that are caused by the **inherent variability** of the analytical procedure from changes that are caused by modifications in the patient's physiology and pathology. The significant change limit is based on the assumption that the **usual standard deviation (USD)** represents day-to-day method variability. As an approximation, the significant change limit is three times the usual standard deviation. Changes greater than the significant change limit are likely to represent a real change in the patient.

Control of quality (process control) and error detection

Once a laboratory's performance criteria are established, a process control system must be put into place. The purpose of this system is to allow continuous monitoring of the testing process (including preanalytical and postanalytical testing) to ensure that either the performance goals are met or that steps are taken to achieve the goals. It is important to recognize the key role of laboratory personnel in the quality process.

Levels of Activity in the Control Process

The control process that we call quality control (QC) is designed to detect error in the measurement system. There are at least three level in this process, each the responsibility of different individuals. For the control process to be most effective, active communication among the individuals within each level of responsibility is crucial.

The first level of the process is the re-

sponsibility of the bench medical technologist and the supervisors. At this level, the control process includes the daily analysis of quality control specimens (discussed in this section) and the review and verification of patient results (results verification) and reports. The technologist is responsible for performing quality control analyses at the appropriate intervals and for determining that, during any given run, there is no significant systematic error in that run. Both the technologists and the supervisor are responsible for reviewing patient data to ensure that no random error exists.

The second level of control ensures that minimal systematic bias enters into the system over a relatively short period of weeks to months. The responsibility for this level of error control is usually shared by supervisors and the laboratory director, though technologists often contribute greatly. The control process at this level requires timely review of the quality control data and proficiency testing that have accumulated over that period of time.

The third level of the control process ensures that the analytical systems are as precise and accurate as possible. This is responsibility of the laboratory director or technical consultant.

The control process at this level requires review of proficiency testing results, knowledge of the levels of precision and accuracy achievable by other laboratories, and, when applicable, the use of accuracy-based standards to verify or correct errors. This level of quality control review occurs over a longer period of time, from months to years.

Testing Quality Control Specimens – Daily Decision Making

The daily preparation and analysis of quality control samples is a regular responsibility of the analyst. The **quality control pools** are analyzed as „known” controls during analysis of patient samples. The values are considered „known” because some attempt has been made

to determine the actual level of each constituent using the procedures employed for routine analysis. The laboratory can estimate the target values of the control samples by repeated analysis (the „true values” being estimated as the mean), use the manufacturer’s estimates of the values, or ideally, determine the values by definitive or reference methods. The frequency of analysis of the QC material is established by each laboratory for each method. CLIA’88 requires the analysis of at least two controls of different values for each **run** (defined as up to 24 hours of stable operation) as do other accrediting bodies with deemed status from CLIA.

Most laboratories use two different pools, one normal and one abnormal. A normal pool contains constituents at concentrations within the non-diseased reference interval, whereas an abnormal pool contains the analytes at concentrations outside the reference interval. Some laboratories may employ three pools – low abnormal, normal and high abnormal – especially when medically significant decisions are made at each level. CLIA allows each laboratory to set its own protocols for chemistry testing assay control samples as long as at least two control samples of different concentrations are assayed every 24 hours. Some states mandate three pools for certain tests. CLIA mandates special rules for blood-gases, requiring as a minimum the analysis of one QC sample every 8 hours of testing and the use of combination of QC samples and calibrators that includes samples with both high and low concentration each day of testing.

The Clinical Laboratory Improvement Amendment also requires the use of one calibrator or control each time a patient sample is analyzed, unless the blood-gas instrument is calibrated at least every 30 minutes. Because of this complexity of blood-gas quality control, some manufacturers have included QC reagents as part of the reagents resident on blood-gas analyzers and have thus assumed a more active role in the QC process. More commonly, how-

ever, the manufacturer of a testing system recommends the testing frequency that should be used as a basis for a laboratory's quality control policy.

Testing personnel must use the data from each quality control analysis to make a decision about the validity of patients' test data. Generally, if the results for a quality control sample are within the accepted target range, technologists may assume that the patients' results obtained during the same run are equally valid and can „accept” the run.

On the other hand, if the results for the quality control pool are unacceptable, the run is not acceptable. The decision to accept or reject an analytical run should be documented and include the decision (either *accept* or *reject*), the analyst's name (or code number), and the date on a work sheet, in a separate log book, on a data sheet, or in the laboratory information system (LIS). Usually, the process of verification of patient data in the LIS by technologists is regarded as implied acceptance of the associated quality control data included in the run. Although the term *run* implies a batch process, current laboratory practice usually has the measurements continuously performed in real-time on automated analyzers. That is, the run is more generally associated with the 8-hour work shift.

Although daily bench-level quality control testing is most useful for detecting systematic errors, it can also be used to detect increases in imprecision. However, random errors, which occur unpredictably, are not usually detectable by a quality control system. Random errors can be detected only by review of reported problems and patients' results.

How to choose a quality control pool

Quality control material should have a matrix that closely matches that of the specimens in the analytical run. This means that if the run includes cerebrospinal fluid, serum and urine, then controls composed of cerebrospinal fluid (CSF), serum, and urine should also be in-

cluded in the analytical run.

Because the quality control material is analyzed in every run along with patients' specimens, large amounts of control material are needed each year. Several sources currently exist from which a laboratory can obtain sufficient quantities of quality control material: (1) commercial lyophilized pool material; (2) commercial stabilized liquid pools; and (3) frozen, pooled, patient specimens. Patient serum is more frequently used than plasma because it is more readily available and is less likely to include precipitated material. Frozen liquid or pools that have been clarified (with material that reduce turbidity) generally show smaller standard deviation than do lyophilized pools. The smaller imprecision errors of the liquid pools derive, in part, from the absence of the errors involved with the lyophilization and reconstitution processes. However, the liquid pools may experience greater instability errors associated with shipping batches of a lot to the customer. It is important to select a pool with a matrix that interacts least with the methods employed in the laboratory. Notice that control pools prepared in the laboratory from pooled patient samples (serum, plasma, urine and CSF) can be contaminated with viruses; thus it is essential to test each specimen or group of specimens and the final pool for harmful viruses. Therefore, the following statements apply to *all* specimen pools used for quality control. First, all pooled human material should be monitored for the human immunodeficiency virus and the hepatitis B virus. No pools should be used if there is evidence of either virus. Second, all control material requires refrigerator or freezer space for storage of a 1- to 2- year supply. Alternatively, commercial distributors may supply quantities from a single lot number of stored material on a monthly or quarterly basis so that the laboratory can use the same lot number over 1 to 2 years. This helps bring long-term stability to the quality control process, though the possibility of shipment-to-shipment variations within

the lot must be considered.

Some professional groups and manufacturers offer participation in **regional quality control** programs in which laboratories use the same batch of pooled serum. This offers both scientific advantages and cost benefits. The comparison between laboratories can help predict how similar testing systems (peer groups) will perform in proficiency testing. This comparison becomes more valuable when the accuracy of the quality control pool is established by reference or **definitive methods**.

Preliminary Considerations for Estimating Limits for Quality Control Pools

Unless the true value of a pool is established by definitive or reference methods, the target values are only averages of repeated measurements of the pool. The average temporary or average final target values of the quality control pool are the estimated concentrations of each analyte within the pool. Each laboratory usually establishes its own average target values for the analytes by performing the laboratory's test procedures on each pool. CLIA'88 allows the pool's manufacturer to establish target values, with the laboratory confirming that each target value is applicable to its testing system.

When new target values are established for a new lot of quality control material, it is important to be sure that, during the data collection period, the analytical systems perform according to normal performance specifications. The new lot of quality control material should be tested in parallel with the current lot of quality control material. If the analytical data from the current quality control material indicate satisfactory performance of the methods, the data for the new lot can be assumed to be valid. When a quality control system is being set up for the first time, the current methodology is accepted as valid if the method meets performance specifications. The choice of the laboratory's testing method (or testing system) is based on experience with medical usefulness,

significant change limits, **external quality control** and accuracy comparisons, and quality control performance.

Three approaches can be used to establish the limits of acceptable values for a control pool. One method is to use the medically values for a control pool. One method is to use the medically allowable error for choosing the range. Another, more usual, approach is to estimate the target value and usual standard deviation (SD) for the method and use some number of SDs to establish the range. The third technique is to employ the more statistically accurate method of **power curves**.

Setting Quality Control Limits by Power Curves

The design of specific control rules for a laboratory requires a five-steps process that includes (1) defining total allowable analytical error, (2) estimating the method's actual standard deviation and bias at the medical decision concentrations, (3) determining the systematic and random error that must be detected by the control system, (4) determining the probability level used for error detection (i.e., do you want to detect 90%, 95% or 99% of errors?) and (5) plotting and inspecting the power curves to determine the number of control specimens that should be tested per run. In general, the most difficult part of these evaluations is determining how much error is allowable.

Westgard (www.westgard.com) used these power curves to develop a series of specific control guidelines, popularly called the „Westgard rules”. The rules, which are used to determine whether an analytical run is out of control, are written in shorthand as follows: (1) 1_{2S} , $1_{2.5S}$, and 1_{3S} mean one control value exceeding two, two and one half, or three standard deviations, (2) 2_{2S} means two control values exceeding two standard deviations, and (3) R_{4S} means the range of two control specimens exceeds four standard deviations. For many testing situations the sequential application of the

$1_{3S}/2_{2S}/R_{4S}$ set of control rules allows two control specimens to give sufficient error detection for a single run. These rules mean that the run is rejected if *any* of the following happen: (1) 1_{3S} , if one control value differs by more than three standard deviations from the mean value, (2) 2_{2S} , if two control values differ by more than two standard deviations from the mean value, and (3) R_{4S} , if the range between two controls in the same run exceeds a combination of four standard deviations. The first two rules will detect excessive bias, whereas the last rejects the run because of excessive imprecision.

Notice that, for rejection, the control value should exceed the control limit, not just be equal to that value. For many chemistry tests, power curves allow cost-effective detection of significant total errors (based on clinical usefulness) when two controls are used and the limits are set somewhere between 2.5 to 3.5 standard deviations. For this reason, many use 3.0 usual standard deviations as a generalized control limit. For best implementation of Westgard rules, the laboratory information system (LIS) or the analyzer must have the proper software present to support this level of quality control checks. A more sophisticated approach to quality control will minimize run rejection and, at the same time, ensure the quality of patient results.

Detection and resolution of quality problems

The out – of – control decision

A testing system is designated as „out of control” when the validity of the results is not considered to be appropriate.

The conditions for an out-of-control determination should be set by each laboratory; as a minimum, the criteria for an out-of-control decision include the following elements:

1. Control values exceed predetermined out-of-control limits within a specified period.

Technologists must be directed to document their response to every control value that exceeds the established limits.

2. A method is determined to have an inappropriate reference interval; if the range is not immediately correctable, the method is „out of control”.

3. A method demonstrates unacceptable imprecision, nonlinearity or interferences. Interferences usually are limited to specific specimen types or substances.

4. The laboratory director, section director, or technical supervisor declares the method out of control for other reasons.

Detection of Quality Problems

Computer assistance. The target values and limits for acceptable results that are established for each control pool are used in daily practice to detect analytical problems. A control result can be reviewed in a variety of ways by a technologist to evaluate acceptability. The technologist can simply compare the result with the posted range. This limits the technologist’s ability to employ the Westgard rules or to evaluate the **trend** of previous results. More complex selection rules are now available as part of some computer programs, either on the instrument or as part of the laboratory’s information system (LIS). Computer assistance allows real-time review of control results, early detection of QC problems, and better documentation of the quality control process.

Levey-Jennings plot. Current quality control data are best interpreted in the context of previous QC results as described above. In order to facilitate this goal, the data obtained from daily analysis of quality control pools can be plotted to give a visual presentation of the data. The most common visual analysis is the **Levey-Jennings plot**. Levey-Jennings plots are usually available on the LIS or on the instrument performing the assays, obviating the need to plot these QC results manually. Levey-Jennings plots should be routinely evaluated by

technologists and supervisory personnel looking for trends or shifts in the data that could indicate problems in the testing system.

Calibration and quality control

Controls may not be used as calibrators. Controls and calibrators must be different because each has a separate and important function. Calibrators set the reported values accurately, whereas controls verify the stability and accuracy of the calibration and the testing system. However, for those tests that do not have suitable controls available, CLIA '88 allows calibration materials to be used as controls. For evaluation of the system's stability, in these cases it is best to find calibrator materials other than those used for calibration of the testing system.

A commercially available calibrator has an assigned value that the manufacturer establishes by using a definitive or reference method or by using reference materials (traceable to **primary standards**). The calibrator is then used to set the value reported by the laboratory's method or instrument. This process establishes correspondence of the instrument output signal with known concentrations. Differences between an aqueous and serum matrix can affect the transfer of known concentrations to a reported patient result. These matrix differences include turbidity, surface tension, which can affect sample pipetting, interactions between analytes and proteins, and the effect of the volume fraction occupied by protein or the other large molecules (especially lipoproteins) on the actual concentration of the analytes.

Calibrators are usually purchased in lots large enough to last 12 or more months. It is recommended that a new lot of calibrator material be tested 6 weeks before it is used. This time delay allows the laboratory to detect any systematic bias between the values of the current and the new calibrator. Bias in a new lot of calibrator is detected when changes are seen in

the mean value of quality control pools or patients test results. Some testing systems do not allow calibrators (especially calibrators from other system) to be run as an unknown because of matrix mismatch. Often a calibrator will have assigned values that don't represent actual analyte values. These assigned-value calibrators are designed to calibrate testing system to produce accurate test values when patients samples are used.

A laboratory that wishes to change a manufacturer's calibration set point must document that the change does not adversely affect the method's performance specifications. Some of the newer analyzers employ a two-dimensional bar code with specific calibration associated with the particular lot of the reagents. In this case, the manufacturer provides one or two point „adjusters” or calibrator-like reagents to refine the calibration curve prior to placing the reagents into use. Of course, controls are subsequently run to verify the accuracy of such factory calibrations.

Quality Control of Reagents Changes and Instrument Maintenance

Each lot of reagent or separate shipment must be evaluated for quality before it is put into use. The laboratory can show that new lots or shipments of reagents (including calibrators and quality control pools) are acceptable if, after their use, the control values do not change significantly. It is also a good practice, after any maintenance is performed, to test a set of controls and run several patient samples from a previous batch before testing is resumed. Maintenance problems can lead to an „action-limits” situation because operating parameters may be changed. A chronological record of all reagent changes, instrument repairs, and maintenance procedures along with any calibration verification tests must be kept.

External quality control programs

Accuracy Control Is Required by CLIA'88

CLIA'88 requires that all laboratories holding a certificate that allows testing of moderately or highly complex tests must participate successfully in proficiency testing. Proficiency testing (PT) specimens are used to evaluate the adequacy of laboratory performance in all laboratory specialties. The analyst must test these specimens in the same manner as patients' specimens. Historically, PT has been part of a volunteer peer review and educational process. Proficiency testing is now regulatory, and failure on PT has serious penalties. However, the value of proficiency testing is the provision of independent validation of the internal quality control programs. Because the analyst does not know the target value of the PT sample, it is difficult for the operator to influence the results. These programs, if properly used, can give an estimation of the inherent accuracy of a system, at least as compared with a peer group or to the overall mean.

Continued or significant deviations from the PT target levels, even if there is no failure, should alert the laboratory to a possible accuracy problem. If a method's USD is not significantly smaller than the comparative group's SD, that method is at increased risk for PT failure.

An *estimation* of a system's bias can also be made from proficiency testing performance. To do this, evaluate the specific test method's observed values against a comparison value, which is either the mean value reported for all similar methods (peer group mean), the mean value for all methods, or the definitive method value. Bias is calculated by subtracting the comparison value from your method's value. The algebraic sign shows whether your method's value is higher (positive bias) or lower (negative bias) than the group mean. Notice that comparison to a peer group mean or even

to the mean of all participants doesn't establish accuracy. These comparisons show bias only when the comparison value is the true value. Certainly repeated bias on proficiency tests must raise the suspicion of a true bias and will require that additional steps be taken to either prove or disprove a real bias.

Quality Control Procedure for Chemistry – Dynacare Kasper Medical Laboratories

Dynacare Kasper Medical Laboratories is a full-service laboratory covering all laboratory medicine and is accredited by the American College of Pathologists (CAP) and the Alberta College of Physicians and Surgeons. The chemistry department is highly automated with many analyzers, some of which are attached to an automated sample delivery system.

Internal Quality Control

1. All controls received are:
 - a. labeled as to date of receipt,
 - b. logged into control inventory log book;
 - c. stored as per manufacturer's specification.
2. Reconstitute lyophilized controls as follows:
 - a. consult manufacturer's specifications and add the required amount of Type I reagent grade water using a Class A volumetric pipette,
 - b. label the vial with the date and time (if time sensitive) of reconstitution, and initials of person reconstituting the control,
 - c. allow reconstituted controls to equilibrate for the time stated by the manufacturer,
 - d. visually check control before use to ensure that controls are dissolved. Check for clarity and that contamination or turbidity are not present.
3. Store controls as per manufacturer's rec-

ommendations when not in use. Discard controls according to manufacturer's stability.

4. Quality control ranges for new unassayed controls are established by parallel analysis with current controls. New control means are established with a minimum of 20 values. Assayed control values must be verified corresponding to the methodologies by the laboratory for quantitative tests.

5. Depending upon availability more than one level of control must be used for each analyte (i.e. low, medium and high).

6. Controls are usually positioned after calibrators and prior to patient samples. Additional controls are assayed at intervals depending on type of analysis and number of specimens to be analyzed.

7. All QC values are entered into the MySys laboratory and are monitored for trends or shifts using rules defined in MySys laboratory.

Daily quality control routine

1. Review control results for the following:
 - a. values are within acceptable limits,
 - b. review controls which are not within acceptable limits and add appropriate comments. Notify senior tech.
2. Document any reagent lot number changes, instrument changes, or any other changes that may affect the results obtained.

Internal Quality Control

All staff must follow this procedure:

1. Verify that control results are within acceptable limits.
2. If control values are not within acceptable limits, add appropriate comments and troubleshoot as required. Notify Tech II or Team Leader.
3. When a test suddenly and repetitively yields unacceptable values, that cannot be corrected, check with the Tech II and review methodology.
4. Document the following in the appropriate log book along with the date and initial:

- a. Reagent lot number changes
- b. Instrument changes
- c. All other changes that may affect the results obtained.

The Tech II or designate must:

1. Under function QC, pull Levey Jennings graphs for each control and analyte.
2. Review the statistics on Levey Jennings graphs:
 - a. Compare established mean to monthly mean.
 - b. Trend or shift in values.
 - c. %CV – changes in CV from previous month.
 - d. Evaluate precision compared to expected precision.
3. Review external QC results for trends, shifts and/or outliers.
4. Review patient means and instrument correlations and linearities.
5. Document any remedial action required or make note if further evaluation to follow.

When a test suddenly and repetitively yields unacceptable values, that cannot be corrected, check with senior staff and review methodology.

The Clinical Chemist reviews internal QC every 3 months.

Quality Control- Westgard Rules

Westgard Rules are designed to detect random and systematic errors in analytical test systems. The rules are used to evaluate data both from within run (data in same run) and between run (data from previous run), *Table 1*.

If all normal and abnormal control results are within $\pm 2SD$ of the mean established for the test, patient results may be reported.

Random error is detected with R13S and R12S rules.

Systematic error is detected with R22S, R412 and R102 rules.

R12S. Warning Rule

One control is outside $\pm 2SD$

- Possible error within the method but is not

considered cause for run rejection.

- When violated, the remaining rules must be assessed.
- Violation of any of the remaining rules is cause for rejection of the run and patient results are not released.

R22S. Two consecutive control results exceed $\pm 2SD$ on the same side of the mean (usually systematic error).

- If two consecutive control results exceed $\pm 2SD$ on the same side of the mean, hold subsequent results.
- Proceed with troubleshooting the procedure or instrument. Notify Tech II or Team Leader if the problem is not resolved.
- Do not report patient values until the controls are within $\pm 2SD$ and the patient samples have been repeated.
- Repeat random specimens whose results have been previously released.
- Patient results may be sent in the control range where the controls are acceptable.

R13S. One control is outside $\pm 3SD$.

- Usually an indicator of a random error.
- Repeat control, troubleshoot if necessary and document.

RR4S. Range rule more than 4SD difference in consecutive controls.

- Usually an indicator of random error or poor reproducibility.

R41S. Warning Rule

Four consecutive controls with a combined range of greater than 4SD in either direction of the mean.

- Accept the run.
- If the another rule is also violated, reject the run. Patient results must not be released.

Table 1. Westgard rules used to detect errors from within and between run

Within Controls	Across Controls
R12S, R13S, R22S, RR4S, R412	R22S, RR4S, R412, R102

- Proceed with troubleshooting. Notify Tech II if the problem is not resolved.

R 412. 4 results in a row outside of 1SD with one of these results outside of 2SD.

- Indication of a systematic error and trend,
- Some action is required as this trend may be more serious than R102,
- Repeat control, review performance, troubleshoot and document.

R10X. Warning rule

Ten consecutive controls on the same side of the mean (systematic error).

R102. Ten in a row on one side of the mean for either Level 1 or 2 (within) OR ten in a row on same side of mean combining Level 1 & 2 (across) PLUS one of these 10 is $> 2SD$.

- Repeat the control, but more importantly review performance history checking manual plots or by using function Levey-Jennings.
- Systematic error or trend indicator.

Rules violated

Accept or reject control results as indicated in *Table 2*.

External Quality Control

External quality control surveys are an integral part of the quality assurance program.

The Chemistry department is enrolled in the following programs:

- College of American Pathologists (CAP)
- Accutest
- Bayer Urinalysis Survey
- HealthMetrx
- Centre de Toxicologie du Quebec
- Centers for Disease Control and Prevention

Table 2. Acceptance or rejection of control results.

Rules Violated	Accept	Reject
R1 _{2S}	X	
R1 _{3S}		X
R2 _{2S}		X
RR _{4S}		X
R ₄₁₂		X

(CDC Atlanta)

- Health Canada
- Wisconsin State Laboratory of Hygiene (NSLH).

An external QC survey is processed as follows:

1. Quality Assurance (QA) Department receives and delivers the survey samples, survey instructions and forms to the department.
2. Chemistry staff:
 - a. Processes the survey samples as patient specimens.
 - b. The samples are repeated only when they fall within the same criteria where a patient would be repeated. No extra or special steps are taken.
 - c. Fill out the survey form and forwards the form and raw data to the Tech II or Team Leader for review.

Acceptable results

If results are within the allowable limits and accepted by the survey program:

1. Quality Assurance Department sends a copy of the final results to the department.
2. Chemistry Manager and Tech II or Team Leader review and sign the final data and file it in the appropriate department survey binder.

Unacceptable results

If results are outside the allowable limit and rejected by the survey program:

1. Quality Assurance Department sends out result summary sheets to the department.
2. Tech II or Team Leader:
 - a. Directs staff to repeat the survey material (if applicable). The following analytes are unstable and are not repeated: Cl, CO₂, ALP, TBIL, CBIL, CK, OSMO, LD, Microscopic Urinalysis, Macroscopic Urinalysis.
 - b. Fills in the result summary form and signs it.
 - c. Makes a photocopy of the completed signed form and files it along with the repeat raw data in the appropriate department survey binder.

- d. Submits the original form to the Chemistry manager for review and signing.

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