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Beaumont

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New Chemistry Test Introduction

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The purpose of this document is to provide the staff with guidance for evaluation studies required on all new methods introduced into the chemistry section. This will help standardize data summary and document storage.

B. This procedure applies to tests classified as moderate or high complexity under the Clinical Laboratory Improvement Act (CLIA) '88 guidelines and includes the following test categories:

1. Individual procedures on multi-channel instruments
2. Individual procedures on single channel instruments
3. Manual procedures
4. Qualitative Tests

II. PROCEDURE:

A. Prior to reporting patient results data must be obtained and retained on file, which verifies that the laboratory is achieving manufacturer's performance specifications for any test that is Federal Drug Administration (FDA) approved. These performance specifications include, where applicable:

1. Accuracy
2. Precision
3. Sensitivity
4. Specificity
5. Reportable Range/Reference Range

B. For specificity assessment, information documenting the likelihood of interference by substances which are likely to be present in the test sample other than the analyte should be evaluated. For FDA approved methods, data provided by the manufacturer may be used for this, and it should be included in the procedure description. According to the following excerpt from CLSI EP07 A2 (Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition), Section 9.3.2, this is acceptable.

    1. Interference is a characteristic of the method and the clinical specimens, and a comprehensive interference evaluation may be beyond the capability of the laboratory. The laboratory may accept the manufacturer's criteria and data if it can show that: 1) the substances tested by the manufacturer are relevant to its own population; 2) the criteria used to define interference are appropriate for the medical needs of its clients, and 3) the interference evaluation was conducted using scientifically valid experimental protocols.

C. For tests which are not FDA approved, i.e., modifications of a manufacturer's procedure, methods adopted from literature descriptions of procedures or methods developed in-house, the following additional performance specifications must also be evaluated and documented:

    1. Appropriate Calibration Procedures
    2. Appropriate Quality Control Procedures
    3. Other Appropriate Performance Characteristics

D. The following sections describe in detail, the specific data to be gathered to satisfy each of the above requirements. Once evaluation studies are complete, the data should be reviewed by a pathologist or a clinical chemist and the procedure approved for patient use. All data supporting the performance of the method must be filed and kept for as long as the method is in use. On approval, the procedure must be dated when it was put into use and initialed by a pathologist or a clinical chemist. It must be approved initially by the laboratory director and reviewed biennially thereafter, as part of the general procedure manual review. Discontinued procedures are retained on file for at least two years. When a discontinued test is put back into production, method performance specifications must be verified, and Proficiency Test (PT) assessment performed within 30 days prior to patient test reporting. Competency assessments for technologists must have been performed within 12 months of test resumption.

E. Any changes made to the procedure must be approved by a pathologist or a clinical chemist, have supporting data to document that the change does not affect test results, and be initialed by a manager, a clinical chemist or pathologist. Effort should be made to have the procedure retyped as soon as possible in the appropriate format. Data documenting the acceptability of the change should be filed with the original evaluation data for the procedure.

F. A clinical chemist or pathologist must review and approve result accuracy, automated result flags, and report format, as built in the laboratory information system (LIS) in both pre-production and production environments to assure that patient reports transmitted to the electronic health record (EHR) will be accurate.

III. CLINICAL CLAIMS VALIDATION:

A. For FDA-approved tests, the laboratory must validate clinical claims not included in the

manufacturer's instructions.

B. Note:

1. A clinical claim is a communication from the laboratory to its users (including but not limited to clinicians and patients) regarding a test's sensitivity and specificity, predictive values for a disease or condition, clinical usefulness, cost-effectiveness or clinical utility.
2. To adequately support a clinical claim, the laboratory must perform a clinical validation study, unless the clinical validity of the test is documented in peer-reviewed literature or textbooks. The clinical validation study must include at least 20 samples and must include both positive and negative samples. If the laboratory uses fewer samples, the laboratory director or designee meeting CAP director qualifications must record the criteria used to determine the appropriateness of the sample size.

IV. EVALUATION REQUIREMENTS FOR FDA APPROVED METHODS:

A. **Accuracy**

1. Accuracy may be assessed by assaying any of the following:
    a. Standard solutions prepared to a known concentration
    b. Calibrators of a lot number different from that used to calibrate the method
    c. Quality control materials with assigned values
    d. Proficiency testing specimens for which consensus values are known
    e. In the absence of satisfactory materials above, a surrogate material approved by a pathologist or a clinical chemist may be substituted.
2. At least three such materials with different levels of the analyte should be used. Results should fall within +/- 5 % of the assigned values to be considered acceptable. If results are between 5 % and 10 % different from assigned value, additional materials should be assayed to determine whether a bias exists in the calibration or the method. Consult with a pathologist or a clinical chemist to determine appropriate follow-up. If results differ by more than 10% from assigned value, they should be considered as having bias and investigation should be done to verify the reliability of the calibrator and the validity of the method conditions. Exceptions may occur in cases where very low levels of analyte are being measured. In these instances, acceptability should be judged by a clinical chemist or pathologist.

B. **Carryover**

1. Analyzers which pipette or aspirate samples should be checked for carryover before being put into service, unless they use disposable tips. If the instrument has more

than one sample probe, each should be checked. This check should be repeated annually and after repair or replacement of the primary sample probe or probe wash system. As this procedure is performed to evaluate the probe, it need not be performed for every analyte measured by a given instrument system. A representative analyte should be chosen that commonly displays elevated results or has an extended measurement range.

2. Carryover is defined as the percent of a leading sample that is transferred into the sample following it. It is also referred to as % Interaction and can be quantified by testing a low concentration sample (1), followed by a high concentration sample, followed by the same low concentration sample (2). Using this approach, it is calculated according to the following formula.

$$\% \text{ Interaction} = \frac{[\text{Low Result (2)} - \text{Low Result (1)}]}{\text{High Result}} \times 100$$

3. Acceptable values may vary according to the imprecision of the method and the range of possible values for the analyte and should be judged by a clinical chemist or pathologist. It may also be evaluated by testing a blank sample after a positive sample such as a standard. Using this approach, it is calculated as follows:

$$\% \text{ Interaction} = \frac{\text{Blank Result} \times 100}{\text{Standard Result}}$$

4. A satisfactory alternative is use of the EP Evaluator Carryover module or Microsoft Excel. In this instance multiple comparisons of low samples run separately and after high samples are compared for statistically significant difference.

C. **Accuracy of Dilution**

The accuracy of manually diluted samples should also be verified to validate the appropriate diluent. An elevated sample should be diluted at two different dilution factors and assayed to verify that results are linear with the diluent used. Be certain the original sample does not exceed the stated linear range. Recovered results should agree with the original undiluted value within +/- 10 % or as stipulated by a pathologist or clinical chemist. Analyzers, which repeat tests using auto-dilution, should be verified for dilution accuracy by comparing auto-dilution versus manual dilution before use. Only one dilution need be checked but should be at least a 1:2 dilution.

D. **Correlation Study**

1. In addition to the known standards or controls used above, a correlation study should be done to determine the relationship of results from the new method to those of an existing, reference method. This may be a method currently set up in the laboratory, or it may be a method performed by a qualified outside laboratory.
    a. Include at least 20 patient specimens
    b. Select samples to cover as wide a range of expected values as possible
    c. Samples must not exceed the linear range of either method
    d. Assay the samples by both methods in singlicate, unless the method normally requires duplicate determinations
    e. Repeat discrepant results by both methods, if possible
    f. Subject results to statistical analysis using linear regression analysis

g. Graph the regression plot with the evaluation method as the y axis and the reference method as the x axis

h. Obtain the slope, intercept and standard error of the estimate ($S_{y/x}$) for the regression line, as well as the correlation coefficient for sites that use EP evaluator

2. Proportional bias may be estimated from the slope of the line and constant bias, from the intercept. The regression data, is not useful in identifying which method is contributing the bias.

3. The correlation coefficient and the standard error of the estimate give a measure of the random variability in the data and also do not indicate which method may be at fault. A general guide for acceptability of the correlation coefficient R, is that R^2 should not be less than 0.85 (R=0.92). R depends greatly on the range of the data, however, and in some cases such as sodium, for example, a lower value may still be acceptable.

4. The standard error of the estimate is a measure of the amount of variability in the y value that is not accounted for by the change in the x value and represents the error associated with the y value.

5. If significant bias exists between methods, it may be necessary to add additional samples to more firmly establish the relationship between the two methods. It may also be necessary to revise the reference range for the new method. Consult with a pathologist or a clinical chemist to evaluate acceptability and need for a new reference range.

E. **Precision**

1. Both within-run and day-to-day imprecision should be assessed using either the following guidelines or the CLSI EP05 procedure.

a. Perform 10 replicate assays of two different level materials for each assessment

b. Carry out day-to-day measurements without benefit of any special treatment other than that which would normally be given to routine patient samples, e.g., do not recalibrate if it would not normally be done at that time

c. Compute the mean, standard deviation and coefficient of variation for the within-run and day-to-day imprecision

2. Acceptable performance will be judged by a pathologist or clinical chemist on an individual basis, but generally, the within-run Correlation Variance (CV) should not exceed 5% and the day-to-day CV should not exceed 7%. Exceptions will occur in both directions, such as direct bilirubin, where 7% would be remarkably good and sodium, where 5% would be unacceptable.

F. **Reportable Range**

1. The analytical measurement range (AMR) of the procedure is established by the range of linearity of the method. This must be determined during evaluation of the

method. A manufacturer's suggested range may be used provided it can be verified with a series of specimens which come reasonably close to the stated range.

2. Determine the analytical measurement range using either:
    a. A series of standard solutions prepared in-house
    b. A series of standards purchased from a commercial source
    c. A quality control material or high patient sample which has been diluted
    d. In the absence of a satisfactory material as noted above it is acceptable to utilize "the best material available" as approved by a pathologist or a clinical chemist
3. At least three solutions and, if practical, a zero concentration should be used. The diluent should be as suggested by the manufacturer. If no diluent is specified then a diluent should be selected from deionized water, saline, reagent blank, or a suitable matrix surrogate such as human serum or bovine serum albumin. Plot the results as observed (y axis) versus expected (x axis) on a linear regression or use the EP Evaluator linearity assessment software. Points which deviate by more than 10% from the expected value should be considered unacceptable and the level at which this first occurs taken as the upper limit of linearity.
4. If points scatter about the line by more than 10%, there is a precision problem, and this should be investigated as such. Specimens which exceed the analytical measurement range must be diluted and repeated.
5. The reportable range is the range of values that are acceptable to report. This is the range that is determined by the acceptable maximum dilution relative to the upper limit of the AMR and the limit of quantitation. The reportable range may be defined by a pathologist or clinical chemist according to clinical standards. If it is determined that the manufacturer's reportable range defines the limit of reporting, then that range should be validated by testing the accuracy of the method's maximum dilution. The maximum dilution can be validated as follows:
    a. A patient sample with a high value is selected (preferably a value that exceeds the AMR).
    b. The sample is diluted with the maximum dilution into the AMR. Preferably the resultant value will be below the midpoint of the AMR but above 20% of the AMR. A smaller dilution is made of the same sample. The resultant value should be between 40% and 80% of the limit of the AMR to assure comparable accuracy and precision between the two dilutions.
    c. The results for the two dilutions are calculated using the dilution factors and compared. A difference less than 10% reflects a dilution accuracy of 5% and will be acceptable in most cases, but acceptability of the maximum dilution should be determined by a pathologist or clinical chemist taking into account acceptable clinical variation

G. **Reference Range**

1. A method reference range may be based on a manufacturer's recommendation after measurement range validation or produced independently. Before using a

manufacturer's recommended reference range, results from the patient correlation study or an independent data set should be assessed at Royal Oak for significant differences between the methods. If there is no clinically (or statistically) significant difference, the existing reference range may be used. If a clinically (statistically) significant difference exists, results from the new method may be factored to correspond to the old reference range, or the manufacturer's range can be used.

2. If a new range is to be adopted, either due to a significant difference or because a new method not previously performed in the laboratory is introduced, a series of specimens from individuals presumed normal should be assayed to verify its appropriateness for our patient population. At least 20 samples should be included and if the range obtained appears different, additional samples should be added to eliminate the uncertainty or establish a new range.
3. If a new range is needed:
    a. Include at least 50 samples (100 would be preferable, if possible)
    b. If the data appear approximately Gaussian in distribution, compute the mean and standard deviation of the distribution and use the 95% confidence interval for the range
    c. If the distribution is skewed with a preponderance of values at one end, use the non-parametric, percentile approach and determine the top and bottom 2.5% cutoff values.

H. **Body Fluid Validation**

1. FDA-approved methods intended for whole blood, plasma, serum, or urine may be used for testing non-standard body fluids when validated by the laboratory for acceptable method performance specifications (accuracy, precision, analytic sensitivity, analytic specificity, interferences, and reportable range). Only fluid tests that are known to be clinically useful and appropriate will be validated and performed routinely. Fluid orders must be built in the LIS to allow for only specific test/fluid combinations with appropriate reference intervals and interpretive comments. Unapproved body fluid test requests must be canceled, or the fluid sent out to a reference laboratory with a validated method. Ordering physicians with a unique request based on an unusual clinical situation must obtain approval from a medical director or designee for any in-house testing to be performed on an unapproved fluid.
2. Method performance specifications determined by the manufacturers of FDA-approved methods may be adopted for acceptable validation of nonstandard body fluids by reasonably excluding the existence of matrix interferences which may affect the results reported when testing a particular body fluid. The lab may refer to published literature or perform validation studies to evaluate interferences due to matrix effects that may be pertinent to the specific methods to be used for testing body fluids.
3. The following outlines one approach to fluid validation by studying admixtures of the nonstandard fluid with serum (or plasma or urine as approved by the FDA). Obtain fresh remnant specimens of serum and the body fluid to be validated. Each should have measurable concentrations (within AMR) of the analyte(s) of interest. Test

both fluid and serum without manipulation using the method(s) to be validated. Prepare fluid/serum admixtures in ratios of 4:1, 3:2, 2:3, and 1:4, and test each admixture by the method(s). Compare expected concentrations of analyte(s), based on the dilutions, to the actual measured values. If no matrix interferences are present, then the results should compare within the total allowable error for the method, and the validated method performance specifications for the method(s) may be used for testing that fluid.

4. Written procedures must be in place for the approved nonstandard body fluid tests.

I. **IT Validation**
Using at least one sample validation of the entire testing process from order to result must be completed. This should be done in both pre-production ("TEST") and final production ("LIVE") stages of the IT build process and should include instrument interface testing. The clinical chemist or pathologist reviews instrument printouts, LIS screens, and LIS and EHR report formats to check for accuracy of the test name, the transmitted result, units of measure, and interpretive comments. Additional test patient resulting should ensure correct flagging of abnormal low and high values (reference ranges), critical values, less-than and greater-than values for reportable range, autoverification rules, delta checks, calculations, and any other LIS function needed for accurate patient reports. The clinical chemist or pathologist must approve the IT validation prior to patient testing, or within 24 hours thereafter.

V. EVALUATION REQUIREMENTS FOR NON-FDA APPROVED METHODS / LAB DEVELOPED TESTS:

A. **Accuracy / Precision / Reference Ranges / IT Validation**
Requirements for assessing accuracy, precision, and reference ranges are the same as for FDA approved methods. The primary difference is that new non-FDA approved procedures do not have manufacturer's specifications to assess. Accuracy, precision, reference ranges, report format, and IT validation documentation must be reviewed and approved by a clinical chemist or pathologist.

B. **Analytical Sensitivity**

1. In the CLIA '88 regulations, the term sensitivity refers to the minimum detection limit for the analyte. This is defined as the lowest concentration that can be distinguished from zero in the assay. It may be determined by at least two different approaches and they may yield different apparent values. One approach is to measure a zero concentration solution, zero calibrator or blank solution 10 times and compute a standard deviation for the results. The "sensitivity" is then taken as the value equal to twice the standard deviation. While this approach produces a number, it does not verify in a positive way that the analyte can actually be measured at that level.
2. A better approach is the following:
    a. Dilute and assay a standard solution
    b. Continue diluting and assaying until the result can no longer be

distinguished from zero

c. Take the prior dilution as the "sensitivity"

3. An acceptable application of these two principles in a slightly different format is the "Limit of Blank" and "Functional Sensitivity" modules provided in EP Evaluator.

C. **Analytical Specificity**

1. This refers to the freedom of the method from interference or cross-reactivity with substances other than the analyte.
2. An interference study may be performed by either of the following methods:
    a. Spiking known samples
        i. Assay a sample for the analyte to determine a baseline value
        ii. Add the interferent to be tested in known concentration to the sample
        iii. Reassay for the analyte
        iv. Compare the result to the baseline value to determine any effect of the suspected interferent
        v. If the result is higher, the interferent cross-reacts or enhances the response of the analyte. If the result is lower, the interferent interferes with the measurement or suppresses the response of the analyte.
    b. Assaying samples containing a mixture of potentially interfering substances.
        i. Use quality control materials, test mixtures, proficiency samples, or patient samples containing one or more known substances, and which do not contain the test substance
        ii. Assay the material for the test substance
        iii. If no response is observed for the test substance, all the substances in the sample may be ruled out as cross-reacting. If a response is obtained, further investigation may be necessary to identify the interferent, depending on the magnitude of the response. This may be deemed acceptable for the application.
3. Substances known to interfere in other similar methods and which can be anticipated to be present in samples at concentrations which may affect results significantly, should be evaluated for possible interference.
4. LC/MS procedures should be evaluated for ion suppression. An acceptable means for assessing suppression is to introduce patient samples after workup via chromatography while infusing and monitoring the analyte response. A significant drop in analyte response at a retention time consistent with the expected appearance window of the analyte would indicate unacceptable suppression. Use of isotopically labeled internal standards is encouraged, where possible, as a means for minimizing inaccuracy due to ion suppression.

D. **Reportable Range**
The reportable range for a Non-FDA approved method must be defined and the maximum dilution and diluent defined and validated, or it can be determined that it is necessary to dilute until a number is obtained. This should be specified by a pathologist or clinical chemist. The maximum dilution and diluent should be validated in a fashion consistent with an FDA approved method. Once a maximum dilution is validated any lesser dilution is also acceptable. If it is necessary to dilute to a number, it is essential that the dilution produce a response within the AMR.

E. **Calibration Protocol**

1. In cases where there is no manufacturer's recommendation for calibration, the laboratory must establish the frequency and materials to be used. Generally, for manual procedures, calibration must be done each run.
2. If an in-house procedure is set up on an automated instrument, the stability of the method should be assessed by calibrating and running quality controls at periodic intervals to determine if and when calibration shifts cause control values to drift out of the acceptable range. An acceptable range for the controls for this purpose is a trend of greater than four consecutive controls that produces a mean value exceeding +/- 1.0 standard deviation.
3. Based on results from this study, establish the time interval for recalibrating and the calibrators to be used for the procedure. Enter this information into the operator's manual or procedure description for the procedure.

F. **Quality Control Protocol**

1. As with calibration above, the number and frequency of quality control checks must be established if there is no manufacturer's recommendation. The necessary frequency is again based on the stability of the method.
2. Quality control must be checked at two levels each time calibration is performed. For methods which may not require calibration each run, such as those on automated analyzers, the frequency of quality control checks should be established by performing a stability study similar to that done for calibration frequency. If quality controls are to be run less than once every 24 hours, data must be retained documenting the acceptability of the proposed frequency.

G. **Other Performance Characteristics**

1. If there are other performance characteristics which would be important to verify prior to startup of a method, these should also be evaluated and data which demonstrates the performance filed along with the other evaluation data.
2. Examples would include such assessments as extraction efficiency or retention time precision in a chromatographic procedure.

VI. EVALUATION REQUIREMENTS FOR QUALITATIVE TESTS:

A. **Accuracy and Specificity**

Qualitative tests should be evaluated for analytical sensitivity and specificity via concordance testing either to a reference method or for a known subject population. A 2x2 contingency table is generated to calculate the % Agreement, (true positive + true negative)/number of samples. Additional measures such as sensitivity and specificity also can be assessed at this time. An optimal study would include 50 positive patients and 50 negative patient samples, but disease prevalence may make an optimal study difficult to impossible. In this instance study design should be established in collaboration with pathologists or a clinical chemist to obtain the most reliable assessment possible. An appropriate alternative is use of the EP Evaluator Qualitative Comparison module.

B. **Precision**
Reliability can be assessed through the performance of control materials. At minimum, a positive and negative control should be included with each run for a period of 20 days to determine method consistency. Acceptability should be determined by a pathologist or a clinical chemist. In addition, it is desirable to assess the reliability of the method around the clinical cutoff points. Samples selected to be + or – 20% of the cutoff value analyzed over 20 days can be used to assess whether a method will discriminate between negative and positive samples 95% of the time, assuming a sample at the cutoff point is defined as being positive or negative 50 % of the time upon repeat analysis. This analysis may be inappropriate for methods using cutoff points defined differently and alternate samples and degrees of replication may be suitable and can be performed as specified by a pathologist or a clinical chemist.

C. **Reference Range/Reportable Range**
For FDA approved qualitative tests it may be unreasonable to alter specified method parameters and cutoff points. For methods developed internally or where manufacturer's guidelines for testing pose a significant patient risk it is necessary for the laboratory to adequately assess sensitivity, specificity, precision and appropriate reporting and interpretation specifications. Use of receiver operating curves should be considered for use when evaluating interpretive guidelines. An appropriate tool for use in this regard would be the EP Evaluator ROC Curve Analysis and the Establishing Reference Intervals modules or comparable statistical tools. Study design and acceptability criteria may be amended for suitability by pathologists or a clinical chemist. The reference or reportable range is established at the Royal Oak automated chemistry laboratory and is applicable to all testing sites.

VII. METHOD VALIDATION SUMMARY:

A. A written summary of the validation data is created, and the approval statement included or attached Procedure Validation Form.

B. This document is signed by the person responsible for summarizing the data (e.g., Manager/ Lead MT) and by the person responsible for reviewing the data and approving the new instrument/method for use (pathologist / clinical chemist).

C. A paper copy of this summary and validation documentation will be available on site.

VIII. REFERENCES:

42 CFR Part 405, et al., Clinical Laboratory Improvement Amendments of 1988; Final Rule

CLSI EP07 A2 Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition), Section 9.3.2

Attachments

Architect Carry Over Worksheet.docx

Department LIS Validation Worksheet.pdf

Procedure Validation Review Form.pdf

Approval Signatures

Step Description	Approver	Date
Medical Directors	Muhammad Arshad: Chief, Pathology	1/8/2024
Medical Directors	Jeremy Powers: Chief, Pathology	1/3/2024
Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	12/28/2023
Medical Directors	Ryan Johnson: OUWB Clinical Faculty	12/27/2023
Medical Directors	John Pui: Chief, Pathology	12/26/2023
Medical Directors	Vaishali Pansare: Chief, Pathology	12/26/2023
Policy and Forms Steering Committee Approval (if needed)	Kelly Walewski: Supv, Laboratory	12/26/2023
	Caitlin Schein: Staff Physician	12/21/2023
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	12/1/2023
	Qian Sun: Tech Dir, Clin Chemistry, Path	11/29/2023
	Jennifer Yaker: Mgr, Laboratory	11/29/2023
	Kristen DiCicco: Mgr, Laboratory	11/13/2023

Kristin Russell: Supv, Laboratory	11/8/2023
Katherine Persinger: Mgr, Laboratory	11/7/2023
Christopher Ferguson: Mgr, Laboratory	11/7/2023
Michelle Alexander: Medical Technologist Lead	11/7/2023
Ashley Beesley: Mgr, Laboratory [KG]	11/6/2023
Leah Korodan: Mgr, Division Laboratory	11/6/2023
Kelly Walewski: Supv, Laboratory	11/6/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

Corewell Health

Corewell Health East Laboratory
Clinical Pathology
Royal Oak

Effective Date: 5/17/2023

Architect Carry Over Worksheet

Principle

Carryover is defined as the percent of a leading sample that is transferred into the sample following it. It is also referred to as % Interaction and can be quantified by testing a low concentration sample (1), followed by a high concentration sample, followed by the same low concentration sample (2). Using this approach, it is calculated according to the following formula.

$$\% \text{ Interaction} = \frac{[\text{Low Result (2)} - \text{Low Result (1)}]}{\text{High Result}} \times 100$$

Acceptable values may vary according to the imprecision of the method and range of possible values for the analyte and should be judged by a clinical chemist or pathologist.

Procedure

Perform after Sample Probe Replacement, Probe Wash System Repair or Replacement

Chemistry Analyzers: Use patient samples with **CK <50 and CK >500**. Use patient samples with **Glucose <60 and Glucose >400** for analyzers without CK.

Immunoassay Analyzers: **Stat Probe** use patient samples with **BHCG < 50 and >10,000** or **Troponin < 0.05 and > 5.0**. Routine Probe use patient samples with **TSH <3.0 and >40.0**.

Date and Time:		Instrument:
Low Result (1)	=	using the formula above
High Result	=	
Low Result (2)	=	% Interaction =
Send to Technical Director for review		

Carryover study performed by: _____ Date: _____

Carryover study approved by: _____ Date: _____

Corewell Health

Corewell Health Laboratory
Clinical Pathology
Royal Oak

Effective Date: 05/31/2023

Department LIS Validation Worksheet

Test Name:

Instrument:

LIS Test Code(s):

Identify LIS environment (Live or Test):

Validation Date: **Expected Go Live Date:**

Validation Items	Intended Values
Test name spelling (limit 24 characters)	
Result accuracy (Test normal and abnormal known samples through entire process, including interface and reporting)	
LOINC code(s)	
Decimal places	
Units	
Calculations (to include a second reviewer)	
Reference Range	
Verify Abnormal High/Low Flags	
Interpretive comments	
Automatic comments	
LIS reportable range (</>)	
Verify qualitative results	
Critical values	
Delta checks	
Auto-verification rules	
LIS collection label	
Aliquots / sample sharing	
Outstanding worklist	
Searchable Synonyms in LIS	
EPIC Report accuracy (AAOE if applicable)	
MDCH reportable	
Verify all Group Test components	

Department LIS Validation Worksheet

Unity QC documentation (means/SD)	
LTD updated	

Attach documentation/screenshots and provide to Technical Director for review:

1) Instrument printouts
2) Screenshots of LIS resulting screens
3) LIS Instant Reports
4) Reporting scenarios
5) Screenshot of reference ranges:

Lead/Manager: _____ Date: _____

Technical/Medical Director_____ Date: _____

Beaumont HEALTH

BEAUMONT LABORATORY

PROCEDURE VALIDATION REVIEW

Purpose

Before a new procedure or modification of an existing procedure can be used to report patient results, it must be validated according to guidelines stated in Protocol for New Test Introduction. This protocol requires that data be obtained to document the accuracy, precision, specificity, reportable range and reference range of the new test or procedure. The data attached to this form documents these performance characteristics for the procedure below. In the case of specificity, manufacturer's results may provide that documentation, if they are available. A Medical or Technical Director must sign this form before the procedure can be put into routine use.

Procedure: _____

Instrument or analyzer: _____

The attached validation data has been reviewed by me and the performance of the method is considered acceptable for patient testing.

Authorizing signature: _____

Date: _____

Date approved for routine use: _____

Date of Form: 06/17/2016