HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Method And Instrument Correlation		
Applies To:	Laboratory Section Heads and Lab. Quality Management Officer		
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1. PURPOSE:

1.1 A correlation study is required to verify the comparability of quantitative laboratory results for analyse tested with two or more different methods/instruments.

2. DEFINITONS:

N/A

3. POLICY:

3.1 Each laboratory section must implement a system for ensuring that every method and/or instrument has undergone thorough investigation prior to the use for reporting patient results.

3.2 The study should be performed whenever a new method and/or instrument are introduced to the lab, also every six months from the time of last study.

3.3 Special cause correlation testing may be necessary in the following cases:

- 3.3.1 Failure of periodic monitoring of comparison testing
- 3.3.2 EQA failure
- 3.3.3 Internal QC failure
- 3.3.4 After major instrument maintenance
- 3.3.5 Clinician inquiry regarding the accuracy result

4. PROCEDURE:

4.1 Samples of external quality control (RIQAS) program or QC sample or patient sample were used with different levels (normal & pathological).

4.2 Samples entered on both machines at the same time on different occasions.

4.3 The samples number is at least (n) = 10.

4.4 There was only one technician performing the tests on both machines using the same measures.

4.5 All analysts measured on both machines are included in the correlation study except for those analyses that has a marked reference range difference on both machines for example analyse or those analyses not frequently done on both machines .

4.6 Correlation coefficient instructions:

- 4.6.1 This calculator used to calculate the sample correlation coefficient on http://www.alcula.com
- 4.6.2 Enter the x and y values in the box above (x1, y1, x2, y2, x3, y3, x4, y4, x5, y5).
- 4.6.3 All x's values is in the first line and all y's in the second line.
- 4.6.4 The correlation coefficient will be displayed if the calculation is successful.
- 4.6.5 To clear the calculator and enter new data, press "reset".
- 4.6.6 The correlation coefficient or person product-moment correlation coefficient (PMCC) is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When r is closer to 1, it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal, a signal strong negative relationship between

the two variables. You may use the linear regression calculator to visualize this relationship on a graph.

4.6.7 There are many formulas to calculate the correlation coefficient (all yielding the same result). This calculator uses the following.

$$r = \frac{n\sum_{i=1}^{n} x_i y_i - \sum_{i=1}^{n} x_i \sum_{i=1}^{n} y_i}{\sqrt{(n\sum_{i=1}^{n} x_i^2 - (\sum_{i=1}^{n} x_i)^2)(n\sum_{i=1}^{n} y_i^2 - (\sum_{i=1}^{n} y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2, ... ,xn) are the x values and yi are the y values.

4.6.8 Criteria of Acceptance of Comparability:

4.6.8.1 Slope (0.90-1.10) OR;

4.6.8.2 Y intercepts 0 or closes enough to zero to be clinically insignificant OR;

4.6.8.3 Correlation coefficient (r): best > 0.975

4.6.8.3.1 Exactly -1 : a prefect downhill (negative) linear relationship

4.6.8.3.2 -0.70 : a strong downhill (negative) linear relationship

4.6.8.3.3 -0.50 : a moderate downhill (negative) relationship

4.6.8.3.4 +0.50 : a moderate uphill (positive) relationship

4.6.8.3.5 +0.70 : a strong uphill (positive) linear relationship

4.6.8.3.6 Exactly +1 : a strong uphill (positive) linear relationship

4.6.9 Comparability also can be assessed by calculation grand mean:

4.6.9.1 Select appropriate samples. Ensure that includes 1 sample with a low abnormal as a y value, 1 with normal value and 1 with a high normal value.

4.6.9.2 Run the sample on the 1st instrument in duplicate.

4.6.9.3 Run the sample on the 2nd instrument also in duplicate.

4.6.9.4 Calculate the mean for each ample on both instrument.

4.6.9.5 Calculate the grand mean of mean on instrument #1 and instrument #2.

4.6.9.6 Calculate the difference between the mean of the 1st and 2nd instrument.

4.6.9.7 Calculate the percent difference by dividing the difference (step #6) from the grand mean.

4.6.9.8 Obtain the cumulative CV of your quality control level that is closest to the grand mean from (step #5). This can usually be obtained from the instrument on which you run the control.

4.6.9.9 Divide the percentage difference from step #7 by your CV to obtain correlation ratio:
Grand mean: A + A = X
Difference (Δ): A – A = Z
% difference: Z/X x 100 = ?

Instrument #1				Instrument #2		
	Replicate 1	Replicate 2	Mean	Replicate 1	Replicate 2	Mean
S1			A			A
S2						
S3						
S4						
S5						

4.6.9.10 Acceptance criteria is different less than 6% CV, approval of the correlation results.

4.6.10 The laboratory manager and supervisor will assess the data and decide if additional specimens need to be analysed. After final acceptance, all printouts and raw data sheets must be kept on file for as long as the method is in use and then archived for the time frame required for next correlation.

4.6.11 Document the conclusions on the Method Validation Summary Form.

5. MATERIALS AND EQUIPMENT:

5.1 EP evaluator or other format of correlation for performing correlation study

6. RESPONSIBILITIES:

6.1 The section head is responsible for approval of correlation study.
6.2 Review of the result documents is the responsibility of laboratory quality management officer.

7. APPENDICES:

N/A

8. REFERENCES:

8.1 DAIDS Guidelines for Good Clinical Laboratory Practice Standards.
8.2 Guide to Method Validation for Quantitative Analysis in Chemical Testing Laboratories (ISO 17025), PS15.
8.3 Guide to Method Validation for Quantitative Analysis in Chemical Testing Laboratories issue 4 February 2016.

9. APPROVALS:

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