Method Validation Worksheets

Refer to QA Manual for instructions on using the Method Validation Worksheets. Also, visit the Qualigen, Inc. website at www.qualigeninc.com for “On Q” Training.

1. Verify Accuracy and Precision – this is performed once per analyzer per assay during installation and training.

2. Verify Reportable Ranges (Calibration Verification) – this is performed initially at start up and routinely every 6 months thereafter.

3. Identify your Reference Ranges

hCG - Verify Accuracy and Precision. Run C1 and C2 five times each upon installation.

	C1 (Low Control Range)	**C2** (High Control Range)
1	**Control C1** *Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*	**Control C2** *Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*
2	**Control C1** *Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*	**Control C2** *Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*
3	**Control C1** *Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*	**Control C2** *Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*
4	**Control C1** *Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*	**Control C2** *Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*
5	**Control C1** *Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*	**Control C2** *Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.*

Calculating Accuracy and Precision

From the Control Range Card, enter the Upper and Lower limits as well as the Mean of the control material's acceptable range into the appropriate sections below.

hCG - C1

Lower Limit	Mean	Upper Limit

Calculate the Average of all 5 values (1+2+…+5)/5: AVG = _____

Calculate the Standard Deviation of all 5 values: SD = _____

Calculate the Install Precision Specification: IPS = _____

IPS = 0.8 x SD Spec { If AVG < 10, SD Spec = 1.8 / If AVG ≥ 10, SD Spec = 0.18 x AVG }

Calculate the Chi-Squared Statistic[1] (χ^2_{stat}): χ^2_{stat} = _____

$$\chi^2_{stat} = SD^2 \times \left(\frac{2.5}{IPS^2}\right)$$

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hCG - C2

Lower Limit	Mean	Upper Limit

Calculate the average of all 5 values (1+2+…+5)/5: AVG = _____

Calculate the standard deviation (SD) of all 5 values: SD = _____

Calculate the Install Precision Specification: IPS = _____

IPS = 0.8 x SD Spec { If AVG < 10, SD Spec = 1.8 / If AVG ≥ 10, SD Spec = 0.18 x AVG }

Calculate the Chi-Squared Statistic (χ^2_{stat}): χ^2_{stat} = _____

$$\chi^2_{stat} = SD^2 \times \left(\frac{2.5}{IPS^2}\right)$$

Chi-Squared Statistic (χ^2) statistical analysis is an accepted methodology for precision performance evaluations. Refer to CLSI (Clinical and Laboratory Standards Institute) EP5 approved guideline "Evaluation of Precision Performance of Quantitative Measurement Procedures".

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hCG
Accuracy and Precision

Analyzer SN: _____

		Circle Your Response		
1	Do all control testing values fall within the acceptable QC range?	Y	N	N/A
2	Is the C1 control $\chi^2_{stat} < \chi^2_{crit}$[2]?	Y	N	N/A
3	Is the C2 control $\chi^2_{stat} < \chi^2_{crit}$[2]?	Y	N	N/A

The critical value for the Chi-Squared Statistic (χ^2_{crit}) based on 5 measurements and a 95% confidence level is 7.81.

If you can provide a "Yes" answer in all 3 question categories above, check the box below to accept the manufacturer's claims for accuracy and precision. If the answer in any of the above question categories is No, check the box that you DO NOT accept the manufacturer's claims for accuracy and precision and contact Qualigen System Support.

- ❑ Accept the manufacturer's claims for accuracy and precision
- ❑ DO NOT accept the manufacturer's claims for accuracy and precision

hCG

Verify Reportable Ranges (Calibration Verification) every 6 months

Verify that the FastPack® IP System is accurate to the limits of the reportable range specified by Qualigen, Inc. by using the FastPack® IP hCG Method Verification Kit.

Low **Target** ☐	*Write "Low Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here*
Mid **Range** ☐	*Write "Mid Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here*
High **Target** ☐	*Write "High Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here*

The Low Verifier result must be < 1.8 mIU/mL and the High Verifier result must be > 1000.0 mIU/mL to accept the Manufacturer's Reportable Range. If either result is different than above, record the reportable range based on actual observed values. The mid value must be within the range designated on the range card. If it is not, repeat the test. If any value is out of range after repeating the test, contact Qualigen System Support.

❑ Accept Manufacturer Reportable Range: 1.8 mIU/mL to 1000.0 mIU/mL

❑ DO NOT Accept. Derived Reportable Range: _____

Identify the Reference Ranges for your Practice

Qualigen has obtained samples from 241 individuals (115 males and 126 non-pregnant females). Samples were obtained from apparently normal, healthy blood donors without any clinically abnormal indications. hCG levels were determined using the FastPack® IP hCG Immunoassay in conjunction with the FastPack® IP System analyzer in order to establish the hCG concentrations in the normal population. The expected normal range for the FastPack® IP hCG Immunoassay in males is <1.8 mIU/mL and in non-pregnant females is <1.8 – 3.0 mIU/mL which reflects the expected normal range for the donor population of this study group.

Determine the reference range appropriate for your patient population.

Type of Patient	Your Reference (Normal) Ranges
Normal	
Others:	

❑ OK to begin testing ❑ NOT OK to begin testing

Testing Analyst/Technical Consultant _____ Date _____

Laboratory Director _____ Date _____