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

Testosterone - Verify Accuracy / 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.

Testosterone - 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 = _____

$$IPS = 0.8 \times SD\ Spec \quad \left\{ \begin{array}{l} \text{If AVG} < 200, \text{SD Spec} = 27.8 \\ \text{If AVG} \geq 200, \text{SD Spec} = 0.139 \times \text{AVG} \end{array} \right\}$$

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

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

Testosterone - 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 = _____

$$IPS = 0.8 \times SD\ Spec \quad \left\{ \begin{array}{l} \text{If AVG} < 200, \text{SD Spec} = 27.8 \\ \text{If AVG} \geq 200, \text{SD Spec} = 0.139 \times \text{AVG} \end{array} \right\}$$

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

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

[1] 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".

Testosterone
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

Testosterone

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 Testosterone 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 < 0.23 ng/mL or < 23 ng/dL and the High Verifier result must be > 16 ng/mL or >1600 ng/dL to accept the Manufacturer's Reportable Range. If either result is different than the 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: 0.23 ng/mL to 16 ng/mL or 23 ng/dL to 1600 ng/dL

❑ DO NOT Accept. Derived Reportable Range: _____

Identify the Reference Ranges for your Practice

Qualigen, Inc. obtained serum samples from 125 random males and 173 random females ranging in age from 18 to 94 years. Samples were obtained from normal, healthy blood donors without any clinically abnormal indications. Testosterone levels were determined using the FastPack® IP Testo Immunoassay in conjunction with the FastPack® IP System analyzer in order to establish the testosterone concentration in the normal population. Results are in ng/dL.

| | | | PERCENTILES | | | |
Test Subjects	N	2.5th	5th	Median	95th	97.5th
Males 20-49 years	98	214.1	230.6	550.5	939.1	1009.4
Males >50 years	27	216.2	226.8	439.0	916.0	1004.1
Females 20-49 years	157	<23.0	<23.0	32.0	277.1	318.2
Females >50 years	16	<23.0	<23.0	29.5	142.8	157.8

Note: The expected range reflects the donor population of this study group. Each laboratory should determine their own reference range appropriate for their 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