Reset Form

Test Validation Form
For Unmodified FDA Approved Test

Items to Be Completed Prior to Patient Testing

Complete One Form for Each Test

Instrument	**Test**

Checklist Item	**Yes or No**	**Initial**
Temp and Humidity Records, if applicable, for each day of testing documented by instrument installer and/or testing personnel		
Manufacturer specified functions and safety checks performed and documented by instrument installer and/or testing personnel		
Required maintenance performed and documented by instrument installer and/or testing personnel		
Reagent(s) and calibrator(s) types and expiration dates verified by instrument installer and/or testing personnel		
Controls types and expiration dates verified by instrument installer and/or testing personnel		
Linearity verifications/reportable ranges (for quantitative testing only) performed and approved by Technical Supervisor (at least 3 points covering the reportable range)		
Reference range(s)/value(s) established		
Precision verifications performed and approved by technical supervisor. A minimum of 21 tests, 7tests in each run (intra-run precision) with 3 separate runs (inter-run precision) or manufacturer specified, CLIA compliant precision verification methods: 1. Calculate Mean and C.V. (for quantitative testing only) 2. Must be comparable to the manufacture's published Mean and C.V. (for quantitative testing only) For qualitative testing, the positive or negative or graded test result precisions must be verified in all runs.		

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Accuracy verifications (correlation studies) performed and approved by Technical Supervisor A minimum of 20 tests performed and compared with the same specimens performed on an identical or similar testing system. 1. R Value (Coefficient of Correlation) must be at least 0.90 or greater (for quantitative testing only). 2. The sensitivity (for qualitative testing only) must be comparable to the manufacture's published value. 3. The specificity (for qualitative testing only) must be comparable to the manufacture's published value.		
All validations worksheets/instrument printouts reviewed, initialed and dated by testing personnel (CLS and/or MLT)		
All corrective actions taken during the validations documented by CLS and/or MLT		
SOP written and approved by Laboratory Director		
MSDS filed		
Proficiency testing enrolled		
Testing information entered into instrument/lab information system 1. Test ID/code and descriptions 2. Panel ID/code, testing components and descriptions, if applicable 3. Interface code, if applicable 4. Reference range(s)/value(s) a. Age specific, if applicable b. Gender specific, if applicable		

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c. Specimen type specific (e.g. serum, plasma, urine), if applicable d. Result interpretations, if applicable 5. Test units 6. Test result format; the decimal place must be identical to that of the reference ranges 7. Test disclaimers, if applicable 8. Reportable ranges/values 9. Critical values/toxic ranges, if applicable 10. Calculation formula, if applicable 11. Special rules, if applicable (such as reflex testing, LDL will not be calculated if Triglycerides is greater than 400 mg/dL, etc.) 12. Testing equipment ID/Serial Number traceable electronically and on paper		
LIS test validations performed		
Corresponding CPT code(s) entered in LIS and verified by Billing Supervisor		

Comments:

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Validations Verified by: _____ Date: _____
(Technical Supervisor)

Reviewed and Approved by: _____ Date: _____
(Laboratory Director)