Test Validation Form
For Modified FDA Approved or Lab Developed Test

Items to Be Completed Prior to Patient Testing

Complete One Form for Each Test

Instrument	Test

Checklist Item	Completed On	Completed By
Instrument delivered, set up, installation and operation validation performed and completed by instrument manufacturer. Approved by the technical supervisor		
Room Temp and Humidity Records for each day of testing recorded by testing person and approved by technical supervisor		
Required maintenance performed and recorded by testing person and approved by technical supervisor		
Reagent expiration dates verified by testing person and approved by technical supervisor		
Calibrator expiration dates verified by testing person an approved by technical supervisor		
Controls expiration dates verified by testing person and approved by technical supervisor		
Instrument linearity performed and passed by testing person and approved by technical supervisor Refer to Validation Plan and Validation Summary		
Precision performed by testing person and approved by technical supervisor Refer to Validation Plan and Validation Summary		

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Analytical sensitivity Refer to Validation Plan and Validation Summary		
Analytical specificity to include interfering substances Experiment Refer to Validation Plan and Validation Summary		
Reportable range. Establish range and enter range into instrument/computer [LIS] Refer to Validation Plan and Validation Summary		
Reference intervals (normal values) Refer to Validation Plan and Validation Summary		
Any other performance characteristic required for test performance Refer to Validation Plan and Validation Summary		
Determination of calibration and control procedures. Refer to Validation Plan and Validation Summary		
Instrument printouts have initials and dates of review and approval		
Corrective action taken to obtain accurate test results must be recorded and approved		

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Checklist Item	Completed On	Completed By
Develop process for accuracy at least twice per year [proficiency testing] Refer to Validation Plan and Validation Summary		

Enter test into lab information system
  1. Test ID number
  2. Test Normal Range(s)
     a. Age
     b. Sex
     c. Other
  3. Test Units		

Assign test to work station		
Assign test to position on test report		
Assign test to billing code (CPT) and any necessary ICD-10 requirement(s)		

Corrective Action: Attach Documentation

_____

_____

_____

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Approved by:_____ Date: _____

Title: _____