

CLINICAL LAB TRACER AUDIT CHECKLIST

Unit/Lab: _____

Specimen #: _____

Date of Audit: _____

Test(s): _____

Auditor: _____

Date of Original Testing: _____

Sample and Form	Y/N	Comments
Do LIMS dates match specimen form?		
Were demographics, etc. from form entered correctly into LIMS?		
Is specimen form labeled correctly?		
Was current specimen form used?		
Was all required information provided on form?		
Test Information		
Is information on website current?		
Is information in "directory of services" current?		
Test Report		
Is Report on Web?		
Does Web Report match LIMS report?		
Does report contain all required data elements?		
Are there any errors/grammatical or otherwise on report?		
Are appropriate comments present for LDTs and ASRs?		
Analytic		
Is SOP up-to-date and approved by Director?		
If tested manually, are all worksheets and logs complete and available?		
Was QC tested as required and were results acceptable for reporting of testing?		
Was information entered into LIMS correctly?		

Clinical Lab Tracer Audit Checklist

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Lab Audited: _____ Date of Audit: _____ Specimen #: _____

Analytic (continued)	Y/N	Comments
Is there documentation of reagents used, lot numbers, expiration dates, etc.		
Were all QC/reagents, etc. w/in expiration date?		
Is there documentation of verification/supervisory oversight?		
If there were any problems, is there documentation of what happened and any corrective actions?		
If automated procedure: are there calibration records?		
Are there maintenance records for any testing equipment?		
Are temperature records available and in range for day(s) for testing?		
Are there product inserts/assay sheets for materials used in this testing?		
Was last proficiency testing performed and acceptable prior to testing date?		
Did testing person have appropriate training and/or competency within the last 6mo-1 yr?		
If test system was implemented since April 2015, is there validation documentation?		

Other Items / Comments: