Specimen Collection Manual

Eurofins Document Reference	1-D-LB-SOP-9043768	**Type of document**	SOP - Standard Operating Procedure
NTD Labs SOP ID	GEN-2-043	**Division**	1-D Clinical Diagnostics Services
Effective Date	Aug 23, 2018	**Business Line(s) / Unit(s)**	(1-DU) Clinical Diagnostics US : (2-59) Clinical Diagnostics Services North-East US : (EUUSME2) Eurofins NTD (US)
Status	Effective	**Periodic Review Date**	Aug 22, 2020
		Functional Area	LB - Laboratory

Written by	Terrence Hallahan
Functional Document Owner	Eurofins D CDS US Quality Management Department; Eurofins D CDS US Laboratory Management; Eurofins D CDS US Quality Control Department
Review and Approval	• Reviewers: Stephanie Zichi; Margaret Palladino; David Krantz; Norman Moore; Christina Deer; Lisa Schmitt; Jonathan Hayden • Approver (Laboratory Director Only): Terrence Hallahan
Reason for Revision	Attachment Q and R need to be added to the references section and linked to in the related documents field after they have been corrected.

Revision Log

Date	Rev.	Author	Description
May 18, 2018	2	Eurofins D CDS US Quality Management Department; Eurofins D CDS US Laboratory Management; Eurofins D CDS US Quality Control Department	Update to remove outdated information, including old company name.

Electronic Signatures

Margaret Palladino;Review;Aug 1, 2018 2:01 PM EDT
Stephanie Zichi;Review;Aug 1, 2018 2:31 PM EDT
Christina Deer;Review;Aug 1, 2018 4:18 PM EDT
Jonathan Hayden;Review;Aug 2, 2018 1:22 PM EDT
Norman Moore;Review;Aug 2, 2018 2:18 PM EDT
Lisa Schmitt;Review;Aug 6, 2018 3:23 PM EDT
David Krantz;Review;Aug 8, 2018 1:54 PM EDT
Terrence Hallahan;Approval;Aug 9, 2018 5:24 PM EDT

1.0 PURPOSE

1.1 The purpose of this document is to provide instructions for the proper identification, collection, handling and transporting of primary specimens.

2.0 SCOPE

2.1 This manual covers primary specimen collection for all tests available at Eurofins NTD Labs

3.0 DEFINITIONS

3.1 Refer to the Electronic Glossary of Terms.

4.0 RESPONSIBILITY

4.1 It is the responsibility of those health care providers ordering tests from Eurofins NTD Labs and collecting primary specimens to follow the guidelines set forth in the Instruction Manual and Test Catalog..

4.2 It is the responsibility of Eurofins NTD Labs Sales, Reporting and Client Services employees to make the specimen collection manual available to clients.

5.0 HAZARDS AND WARNINGS

5.1 N/A

6.0 MATERIALS AND SUPPLIES

6.1 N/A

7.0 PROCEDURE

7.1 The test specific Instruction Manuals are to be made available to those responsible for primary specimen collection, handling and test ordering. These documents contains the following information:

7.1.1 Requisition Forms

7.1.2 General Information

7.1.3 Instructions on Collection of Dried Blood Specimens

7.1.4 Instructions on Collection of Specimens from Venipuncture

7.1.5 Special handling needs between time of collection and time received by laboratory

7.1.6 Labelling of primary samples with unique identifiers

7.1.7 For each test offered by the laboratory the following information is provided

7.1.7.1 Reporting Location

7.1.7.2 Description of the test

7.1.7.3 Analytical Method

7.1.7.4 Patient Preparations

7.1.7.5 Specimen requirements

7.1.7.6 Collection Instructions (including requirement for 2 forms of identification)

7.1.7.7 Additional information

7.1.7.8 Information Related to Electronic Medical Records Interfaces

7.1.7.8.1 Ask on Entry Questions

7.1.7.8.2 Result Codes

7.1.7.9 Supplemental Reports

7.1.7.10 CPT Codes

7.1.7.11 Reference Values

7.1.7.12 Testing Algorithm

7.1.7.13 Consents/Authorizations

7.1.7.14 Disclaimer

7.2 In addition, the Instruction Manual Test Grid is to be made available to those responsible for primary specimen collection, handling and test ordering. The Test grid contains the following information for each test offered by the laboratory

7.2.1 Analytes

7.2.2 Options

7.2.3 Timing of draw

7.2.4 Specimen type

7.2.5 Minimal volume

7.2.6 Transport temperature

7.2.7 Transit allowance (i.e. number of days specimen can be in transit)

7.2.8 Rejection criteria

7.3 The above documents have been approved by the Eurofins NTD Marketing Department.

7.4 Clients can obtain a copies of the Test Grid and individual Test Instruction manuals by either requesting them from Client Services or by visiting the ntdlabs.com website.

8.0 RECORDS

8.1 Electronic copies of the 'Test Grid' and Individual Test Instruction manuals are maintained in EtQ. Archived copies of the instruction manual will be kept for 10 years from the obsolescence date.

9.0 REFERENCES

9.1 GEN-2-043 Attachment A – Instruction Manual Test Grid
GEN-2-043 Attachment B – FirstTrimesterScreen | Fß Instruction Manual
GEN-2-043 Attachment C - PreeclampsiaScreen™|T1 Instruction Manual
GEN-2-043 Attachment D - MaternalFetalScreen|T1 Instruction Manual
GEN-2-043 Attachment E - verifi® from Eurofins NTD Instruction Manual
GEN-2-043 Attachment F - Carrier Screening Instruction Manual
GEN-2-043 Attachment G - Zika Rt-PCR Instruction Manual
GEN-2-043 Attachment H - Zika IgM Instruction Manual
GEN-2-043 Attachment I - AfpTest (for ONTDs) Instruction Manual
GEN-2-043 Attachment J - DoubleScreen | Fß Instruction Manual
GEN-2-043 Attachment K - QuadScreen | Fß Instruction Manual
GEN-2-043 Attachment L - SequentialScreen | Fß Instruction Manual
GEN-2-043 Attachment M - Amniotic Fluid AFP (with reflexive AChE Instruction Manual
GEN-2-043 Attachment N - Amniotic Fluid AChE Only Instruction Manual
GEN-2-043 Attachment 0 – Cystic Fibrosis Carrier Screening (Dried Blood) Instruction Manual
GEN-2-043 Attachment P – BRCA Tesing Instruction Manual
GEN-2-043 Attachment Q – Blood Specimen Collection from Venipuncture Instruction Manual
GEN-2-043 Attachment R – Dried Blood Specimen Collection Instruction Manual