



SCOPE OF ACCREDITATION TO ISO/IEC 17043:2010

CDC – NEWBORN SCREENING AND MOLECULAR BIOLOGY BRANCH

4770 Buford Hwy NE

MS S109-1

Atlanta, GA 30341

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PROFICIENCY TESTING PROVIDER

Valid To: September 30, 2025

Certificate Number: 4190.01

In recognition of the successful completion of the A2LA evaluation process, this proficiency testing provider has been found to meet ISO/IEC 17043:2010, “Conformity Assessment-General Requirements for Proficiency Testing.” Accreditation is granted to this provider to provide proficiency testing samples in the following programs:

<u>Program Name</u>	<u>Matrix</u>	<u>Analytes Measured</u>	<u>Type of Measurement¹</u>	<u>Frequency</u>
Acylcarnitines	Dried Blood Spots (DBS) –	a. Free Carnitine C0(L) b. Acetylcarnitine C2(L) c. Propionylcarnitine (C3) d. Malonylcarnitine (C3DC) e. Malonyl + Hydroxybutyrylcarnitine (C3DC+C4OH) f. Butyrylcarnitine (C4) g. Hydroxybutyrylcarnitine (C4OH) h. Isovalerylcarnitine (C5) i. Tiglylcarnitine (C5:1) j. Glutarylcarnitine (C5DC) k. Hydroxyisovalerylcarnitine (C5OH) l. Hexanoylcarnitine (C6) m. Octanoylcarnitine (C8) n. Decanoylcarnitine (C10) o. Decenoylcarnitine (C10:1) p. 2,4-Decadienoylcarnitine (C10:2) q. Myristoylcarnitine (C14) r. Tetradecenoylcarnitine (C14:1) s. Palmitoylcarnitine (C16) t. Hydroxypalmitoylcarnitine (C16OH) u. Stearoylcarnitine (C18) v. Oleoylcarnitine (C18:1) w. Hydroxystearoylcarnitine (C18OH)	Qualitative	Three times per year (January, July & October)

<u>Program Name</u>	<u>Matrix</u>	<u>Analytes Measured</u>	<u>Type of Measurement</u> ¹	<u>Frequency</u>
Amino Acids And Succinylacetone	Dried Blood Spots (DBS)	a. Phenylalanine b. Leucine c. Methionine d. Tyrosine e. Valine f. Citrulline g. Arginine h. Succinylacetone	Qualitative	Three times per year (January, July & October)
Hormones and Total Galactose	Dried Blood Spots (DBS)	a. Thyroxine (T4) b. Thyroid-Stimulating Hormone (TSH) c. 17 alpha-Hydroxyprogesterone (17OHP) d. Total Galactose (TGal)	Qualitative	Three times per year (January, July & October)
Biotinidase	Dried Blood Spots (DBS)	Biotinidase	Qualitative	Three times per year (January, July & October)
Galactose-1-Phosphate Uridyl Transferase	Dried Blood Spots (DBS)	Galactose-1-Phosphate Uridyl Transferase	Qualitative	Three times per year (January, July & October)
Immunoreactive trypsinogen (IRT)	Dried Blood Spots (DBS)	Immunoreactive Trypsinogen (IRT)	Qualitative	Three times per year (January, July & October)

¹Assigned values are known values determined by proficiency test item formulation.



Accredited Proficiency Testing Provider

A2LA has accredited

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Atlanta, GA

This accreditation covers the specific proficiency testing schemes listed on the agreed upon Scope of Accreditation.

This provider is accredited in accordance with the recognized International Standard ISO/IEC 17043: 2010 *Conformity assessment - General requirements for proficiency testing*. This accreditation demonstrates technical competence for a defined scope and the operation of a quality management system.



Presented this 8th day of October 2021.

A blue ink signature of a person, likely a representative of the accreditation body, written over a horizontal line.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4190.01
Valid to September 30, 2025

For the proficiency testing schemes to which this accreditation applies, please refer to the provider's Scope of Accreditation.