



New York State Department of Health issues CLIA Certificate Number for Renalytix Lab

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Renalytix AI plc (AIM: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announces that the New York State Department of Health has issued a Clinical Laboratory Improvement Amendment (CLIA) ¹ certificate under the Centers for Medicare & Medicaid Services (CMS) to the RenalytixAI commercial laboratory in New York City. This unique CLIA certificate number is an important initial step in the process towards certifying RenalytixAI to conduct commercial operations for testing patients in the State of New York.

All clinical and forensic laboratories and blood banks located in, or accepting patient specimens from, New York State must hold a New York State Department of Health clinical laboratory permit. The RenalytixAI New York Laboratory facility will now therefore be scheduled for an on-site survey by the State of New York Department of Health. RenalytixAI would be eligible for such a permit after successful completion of proficiency testing, on-site survey and validation requirements.

A laboratory can only perform under a CLIA license those clinical diagnostic tests for which the analytic and clinical performance characteristics have been established (i.e. validated), or, if already established (typically by the test manufacturer), verified at the site where the clinical diagnostic test will be performed. The laboratory must also hold the appropriate permit category for the test and must meet all other requirements related to on-site survey standards, personnel requirements, and proficiency testing.

Notes:

¹ The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The objective of the CLIA programme is to ensure quality laboratory testing. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA programme.

² United States Renal Data System – <https://www.usrds.org/adrhighlights.aspx>

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