



New commercial testing facility opens in Utah

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Utah issues CLIA Certificate of Registration to allow patient testing

New laboratory enables five-fold test volume increase to support 2020 commercial goals

Renalytix AI plc (LSE: REXX), a developer of artificial intelligence enabled clinical diagnostics for kidney disease, announces that it has received a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Registration for its newly established clinical laboratory operation in Salt Lake City, Utah.

The Salt Lake City laboratory facility supports the delivery of multiple elements in the Company's 2020 commercial strategy plan, including the scaling-up of test volumes, optimizing sample processing costs and accelerating payor coverage determinations. With the receipt of the Certificate of Registration, the Utah laboratory is now authorised to begin patient testing effective immediately.

Effects of the Salt Lake City commercial laboratory

A primary benefit of the new Salt Lake City commercial laboratory, in combination with the Company's New York City facility, is to enable a five-fold increase in maximum potential processing capacity to approximately 15,000 reportable test results per month across both sites while also providing significant risk mitigation through operational redundancy. The Salt Lake Facility is expected to begin operating in calendar Q2 of this year.

In addition, the issuance of the Utah laboratory CLIA Certificate of Registration allows RenalytixAI to initiate its request for a Local Coverage Determination (LCD) from Noridian Healthcare Solutions, the regional Medicare Administrative Contractor (MAC) responsible for services performed in laboratories located in the State of Utah. Once granted, the LCD applies to payment for *KidneyIntelX™* tests run in the Utah laboratory on patient samples received from all 50 US states. The LCD is expected to take approximately 12 months and would be in addition to both coverage determination policies already adopted by insurance payor CDPHP as announced on 17 October 2019 (RNS: 1517Q), and further coverage determinations the Company may potentially secure from private insurance payors during 2020 and beyond.

RenalytixAI believes that Utah represents an ideal location to meet scaled commercial requirements in 2020 and beyond due to a combination of attractive facility and general operating costs, close proximity to Salt Lake City International Airport, and a qualified pool of diagnostics personnel available for hire.

As a result of the expanded capacity and operational build-out in Salt Lake City, RenalytixAI and AKESOgen mutually agreed to end their testing partnership previously announced by the Company on 13 February 2019 (RNS: 8220P), with expiry effective at the end of 2019.

Update on key personnel

On 3 December 2019, Dr. Michael J. Donovan, PhD, MD, RenalytixAI Chief Medical Officer, was granted a Utah State medical license certifying him to oversee all Salt Lake City laboratory clinical test reportable results in addition to results reported by the New York City laboratory.

RenalytixAI has also recently appointed Kate Ashley, MLS, CQA, RAC, formerly of ThermiGen (a Celling BioSciences Company), as Director of Quality Assurance headquartered in Salt Lake City with a direct line of report to RenalytixAI Chief Executive Officer, James McCullough. In addition, Baljit (BJ) Singh, MBA, MT (ASCP), formerly Lab Director at Quest Diagnostics, has been hired as Head of Clinical Operations overseeing daily laboratory operations in both of the Company's laboratory facilities.

Update regarding CLIA certification

The Centers for Medicare & Medicaid Services (CMS) regulates all clinical laboratory testing performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). To ensure quality laboratory testing, all clinical laboratories must be licensed in order to receive Medicare or Medicaid payments. The CLIA Certificate of Registration issued to RenalytixAI for its Salt Lake City laboratory allows it to now perform non-waived (moderate and/or high complexity) testing at that site, until the laboratory is inspected by the Utah Department of Health to determine its compliance with CLIA regulations. After a successful inspection, CMS will issue a new certificate, a Certificate of Compliance, for the Salt Lake City laboratory. The CMS inspection is expected to take place in the first half of calendar 2020, with subsequent annual inspections run by the Utah Department of Health.

Five states will require a separate out-of-state license before RenalytixAI can provide testing services for their residents: California, Maryland, New York, Pennsylvania and Rhode Island. RenalytixAI has initiated the application process starting with New York State in December of 2019 and expects to initiate the application process for the remaining four states in the first half of calendar 2020. The Company expects the Salt Lake City Laboratory to be licensed to perform testing for residents of all 50 states before the end of calendar 2020.

The New York City laboratory facility is expected to receive CLIA certification from New York State as early as Q2 2020 to be able to conduct commercial patient testing services.

The person responsible for arranging the release of this announcement on behalf of the Company is James McCullough, CEO.

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About Kidney Disease

Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control estimates there that 15% of United States adults or 37 million people currently have kidney disease. It is reported that 9 out of 10 adults with chronic kidney disease do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a “silent killer” because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day 13 patients die in the United States while waiting for a kidney transplant.

*<https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>

About RenalytixAI

RenalytixAI is a developer of artificial intelligence-enabled clinical *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit renalytixai.com