CLINICAL LABORATORY PERMIT

pennsylvania
DEPARTMENT OF HEALTH

Pursuant to the act of September 26, 1951, P.L. 1539 as amended, a Permit to operate a Clinical Laboratory is hereby granted to:

Laboratory Identification Number: 38401

Name and Director of Laboratory:

SCIPHER MEDICINE
ZORAN GATALICA, M.D.
4134 SOUTH ALSTON AVE., SUITE104
DURHAM, NC 27713

Owner:

SCIPHER MEDICINE CORPORATION

ISSUE DATE: March 14, 2021

DATE EXPIRES: August 15, 2021

AUTHORIZED CATEGORIES/TESTS:
CLINICAL CHEMISTRY
NON-SYPHILIS SEROLOGY

Allison V. Beam

Allison V. Beam
Acting Secretary of Health

DISPLAY THIS CERTIFICATE PROMINENTLY
This permit is subject to revocation, suspension, or limitation for violation of the Act or the Regulations promulgated thereunder.

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INFORMATION FOR NEW LABORATORIES

Your laboratory is now licensed under the Pennsylvania Clinical Laboratory Act. The enclosed permit has been issued accordingly.

We have assigned your laboratory the ID number shown on the permit. Please include this number on all correspondence sent to our office.

The laboratory must notify the Bureau within 30 days if laboratory/permit information changes, such as director, name, location, ownership, and test menu. To facilitate this process, the laboratory must complete and submit a Change of Status form to the Bureau of Laboratories.

A current Change of Status Form can be obtained on our web site at http://www.health.pa.gov/labs, in the Applications and Forms section under the Division of Laboratory Improvement.

Once received, changes will be made to both the State permit and CLIA certificate, if applicable.

GUIDANCE DOCUMENTS FOR CLIA-WAIVED LABORATORIES:

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) criteria.

CLIA requires that waived tests be simple and have a low risk for an incorrect result, but they are not completely error-proof. To decrease the likelihood of an incorrect result, tests must be performed correctly, by trained personnel who follow good laboratory practices.

Resources for good laboratory practices for waived testing can be found at:

CDC Resources for Waived Tests at https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx

CDC Ready, Set, Test Booklet at https://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf

GUIDANCE DOCUMENTS FOR CLIA-PROVIDER PERFORMED MICROSCOPIC PROCEDURES (PPMP) LABORATORIES:

PPMP-certified laboratories may perform CLIA-waived tests as well as a limited list of moderate complexity microscopic examinations during the course of a patient's visit.

PPMP-certified laboratories must meet the same CLIA quality standards as laboratories performing moderate complexity tests.

Resources for requirements for PPMP testing can be found at:

CDC Resources for PPMP Tests at https://wwwn.cdc.gov/clia/Resources/PPMP/

CDC PPMP Booklet at https://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15_258020-A_Stang_PPMP_Booklet_FINAL.pdf

GUIDANCE DOCUMENTS FOR OTHER CLIA CERTIFICATE TYPES:

Resources for laboratories with a CLIA Certificate of Compliance or Certificate of Accreditation can be found at:

CMS CLIA Regulations and Guidance at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

Bureau of Laboratories | 110 Pickering Way, Exton, PA 19341 | Phone: (610) 280-3464 | Fax: (610) 450-1932 | www.health.pa.gov/labs