CENTERS FOR MEDICARE & MEDICAID SERVICES CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS

S BEND MED FOUNDATION ELK DONOR CTR 600 E BLVD ELKHART, IN 46514 CLIA ID NUMBER

15D2094358

EFFECTIVE DATE

04/15/2021

04/14/2023

EXPIRATION DATE

LABORATORY DIRECTOR

LAURA J BROADSTREET MT (ASCP

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Monique Spruill

Monique Spruill, Director Division of Clinical Laboratory Improvement & Quality

Quality & Safety Oversight Group

Center for Clinical Standards and Quality

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- If this is a <u>Certificate of Registration</u>, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a <u>Certificate for Provider-Performed Microscopy Procedures</u>, it certifies the laboratory to perform only those
 laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable,
 examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a <u>Certificate of Waiver</u>, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.



