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| Maryland Department of Health<br>Office of Health Care Quality - Laboratory Licensing<br>7120 Samuel Morse Drive<br>Second Floor<br>Columbia, Maryland 21046<br>Phone: 410.402.8025 Fax: 410.402.8213                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>FOR OFFICE USE ONLY</b><br>License #: <u>          RDT-          </u><br><br>Date Rec'd: <u>                                </u> |  |
| <b>Rare Disease Testing Application</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |                                                                                                                                     |  |
| <b>LABORATORY INFORMATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |                                                                                                                                     |  |
| LABORATORY NAME:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | CLIA NUMBER:                                                                                                                        |  |
| FACILITY ADDRESS:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  | MAILING ADDRESS (IF DIFFERENT THAN FACILITY ADDRESS):                                                                               |  |
| CITY/STATE/ZIP CODE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | CITY/STATE/ZIP CODE                                                                                                                 |  |
| PHONE NUMBER:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | CONTACT PERSON:                                                                                                                     |  |
| FAX NUMBER:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  | EMAIL ADDRESS:                                                                                                                      |  |
| <b>LABORATORY DIRECTOR INFORMATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |                                                                                                                                     |  |
| DIRECTOR NAME:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | DEGREE:                                                                                                                             |  |
| CERTIFICATION BY AMERICAN SPECIALTY BOARD (NAME, DATE, NUMBER):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | STATE MEDICAL LICENSE:                                                                                                              |  |
| Rare disease (see COMAR 10.10.01.03(64) for definition of "rare disease") licensure limits the licensee to perform not more than 50 rare disease tests each year on specimens received from Maryland patients (COMAR 10.10.03.06(A)(2)(c)).                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                                                                                     |  |
| PROFICIENCY TESTING (IF NOT ENROLLED IN A COMMERCIAL PROFICIENCY TESTING PROGRAM, PLEASE DESCRIBE THE IN-HOUSE PROFICIENCY TESTING PROGRAM)<br><br><hr/> <hr/>                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |                                                                                                                                     |  |
| LIST RARE DISEASE TESTING INCLUDING PREVALENCE OR INCIDENCE:<br><br><hr/> <hr/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |                                                                                                                                     |  |
| DESCRIBE QUALITY CONTROL PROGRAM:<br><br><hr/> <hr/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                                                                                                                     |  |
| <b>OWNERSHIP INFORMATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |                                                                                                                                     |  |
| NAME AND ADDRESS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | FEDERAL TAX ID (EIN#)                                                                                                               |  |
| <b>ATTESTATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |                                                                                                                                     |  |
| I certify that the information provided in this application is true and complete. I agree to abide by the laws of Maryland governing medical laboratories, and I understand that any willful and knowing false statement or representation, or failure to fully disclose the requested information in this application may lead to a denial of license, or the suspension or revocation of the rare diseases testing license issued to this entity to offer or perform medical laboratory tests. I also understand that compliance with State laws and regulations may not assure compliance with federal requirements. |  |                                                                                                                                     |  |
| SIGNATURE OF LABORATORY DIRECTOR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | DATE                                                                                                                                |  |