| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D2293926 | 06/03/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Chronetyx Laboratories | 3171 Players Club Pkwy, Memphis, TN | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedure manual and staff interview, the laboratory's policy for testing personnel training and competency assessment failed to meet the requirements in Subpart M. The findings include: 1. A review of the laboratory's policy titled "Quality Assurance Plan" revealed the following under the section titled "Performance Evaluation Program": "The laboratory performs yearly training and competency assessment of all laboratory personnel as part of the performance evaluation program. This involves training on SOPs, policies, and processes." The policy did not require training and demonstration of accuracy prior to test performance, did not require a semi-annual competency during the first year of patient testing, did not include a requirement for reassessment of competency prior to reporting patient test results with test methodology or instrumentation changes and did not include the six elements required in Subpart M. The six required elements are direct observation of routine patient test performance, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records, direct observation of instrument maintenance and function checks, assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples and assessment of problem-solving skills. 2. The managing director confirmed the survey findings during an interview on 06/03/24 at 3 p.m. |
| **D5305** | TEST REQUEST |

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| | CFR(s): 493.1241(c)<br><br>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory procedure manual, review of the laboratory test requisition, and staff interview, the laboratory test requisition did not include specimen collection time. The findings include: 1. A review of the laboratory procedure titled "Urinary Tract Infection - Bacterial Identification by qPCR" revealed a specimen stability of "72 hours." 2. The laboratory test requisition did not include collection time. 3. The managing director confirmed the laboratory test requisition did not include specimen collection time during interview on 06/03/24 at 3 p.m. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test records, review of the laboratory procedure manual, and staff interview, the laboratory failed to ensure procedures were approved by the laboratory director before patient testing which began on 05/31/24. The findings include: 1. A review of patient records revealed the first patient for bacterial identification and antimicrobial resistance was reported on 05/31/24 (Lab ID SPCR-240531-000019). 2. A review of the laboratory procedure manual revealed the following procedures that were not approved by the laboratory director before use: Laboratory Safety Procedures and Policies, Quality Assurance Plan, Urinary Tract Infection - Bacterial Identification by qPCR. All procedures were approved on 06/01 /24 after patient testing had begun on 05/31/24. 3. The managing director confirmed during interview on 06/03/24 at 3 p.m. that laboratory procedures were not approved by the laboratory director before patient testing began. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test |

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| | system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory and staff interview, review of the laboratory procedure manual, patient test records, lack of documentation, and exit interview with staff, the laboratory failed to establish specimen stability and transport requirements for the bacterial identification and antimicrobial resistance performed by polymerase chain reaction (PCR) before patient testing which began on 05/31/2024. The findings include: 1. Laboratory observation on 06/03/24 at 9:30 a.m. revealed equipment and reagents used for performing testing for bacterial identification and antimicrobial resistance by PCR. During observation, the managing director stated the laboratory received samples via commercial delivery services that could potentially expose the samples to temperature extremes. 2. A review of the laboratory procedure "Urinary Tract Infection-Bacterial Identification by qPCR" revealed urine sample requirements of urine in a gray top urine transport tube with a specimen stability of 72 hours at room temperature or refrigeration. 3. A review of patient test records revealed the first patient was reported on 05/31/24 (Lab ID SPCR-240531-000019). 4. The laboratory failed to provide evidence of specimen stability studies conducted to establish specimen storage and transport requirements. 5. The managing director confirmed during exit interview on 06/03/24 at 3 p.m. that the laboratory had not performed studies to establish specimen stability, transport, and storage requirements for the bacterial identification and antimicrobial resistance testing performed using PCR. |