

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1023920	(X3) Date Survey Completed 04/05/2019
Name of Provider or Supplier Winnsboro Medical Clinic	Street Address, City, State 3326 Front Street, Suite B, Winnsboro, LA	
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
D0000	A Recertification Survey was performed at Winnsboro Medical Clinic - CLIA ID # 19D1023920 on April 5, 2019. Winnsboro Medical Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing results from the CMS-155D and American</p>

	<p>Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing as evidence by: 1. The laboratory failed to attain a score of at least 80% for the Red Blood Cell and Hematocrit testing. Refer to D2121. 2. The laboratory failed to attain a satisfactory score score of at least 80% for Hematology in Event 3 of 2018. Refer to D2122. 3. The laboratory failed to achieve a score of at least 80% for Red Blood Cells in two of three consecutive events resulting in initial unsuccessful participation. Refer to D2130.</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 155D Report and American Proficiency Institute (API) and interview with personnel, the laboratory failed to attain a score of at least 80% for the Red Blood Cell and Hematocrit testing. Findings: 1. Review of the API Proficiency Testing Records revealed the laboratory did not achieve a score of at least 80% for the specialty of Hematology for the following events: For the 2nd event in 2018 the laboratory received a score of 0% for Red Blood Cell (RBC). For the 3rd event in 2018 the laboratory received a score of 0% for Red Blood Cell (RBC). For the 3rd event in 2018 the laboratory received a score of 40% for Hematocrit (HCT). 2. In interview on April 5, 2019 at 11:40 am, the Technical Consultant stated the laboratory stopped testing of RBC and contacted the state office. The Technical Consultant further stated the laboratory contacted theCell Dyn Emerald analyzer field service representative to perform maintenance and will start testing after a successful API survey is reported.</p>
<p>D2122</p>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing results, the laboratory failed to attain a satisfactory score score of at least 80% for Hematology in Event 3 of 2018. Findings are: 1. Review of CASPER Reports 0155D along with API Proficiency Testing Records revealed the laboratory received an overall score of 70 % for Hematology in the second event of 2018.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the CMS-155D and American</p>

Proficiency Institute (API), the laboratory failed to achieve a score of at least 80% for Red Blood Cells in two of three consecutive events resulting in initial unsuccessful participation. Findings: 1. Review of proficiency testing records and the CMS 155D Report revealed the following unsatisfactory proficiency testing scores for Red Blood Cell (RBC) resulting in unsuccessful participation: a. 2018 Event 2: Score of 0% b. 2018 Event 3: Score of 0%

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have detailed written policies and procedures for: a) Detailed policies and procedure for an Individualized Quality Control Plan (IQCP): detailing who is going to perform, what is going to be performed, when it is going to be performed, where it is going to be performed and how it will be performed. What data is needed to support the IQCP and how that data will be retained. Also what will be the acceptability criteria, and who needs to review and sign off on the IQCP and when to implement the outcome. b) Proficiency Testing: how to handle failures and what corrective action to take when the laboratory fails two (2) out of three (3) events for the same analyte or specialty/subspecialty for the first and second failures. 2. In interview on April 5, 2019, the Technical Consultant confirmed the above policies were not included.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to include the in house quality control (QC) data to support the reduction of frequency of QC in their Individualized Quality Control Plan (IQCP). Findings: 1. Review of the laboratory's policy and procedures revealed the laboratory utilized IQCP to reduce the frequency of quality control for the following: a) Chlamydia b) Neisseria Gonorrhoeae c) Trichomonas Vaginalis d) Biofire FilmArray Respiratory Panel (includes Adenovirus, Coronavirus 2298, Coronavirus HKU1, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Respiratory Syncytial Virus, Bordetella Parapertussis, Bordetella Pertussis, Chlamydia Pneumoniae, and Mycoplasma Pneumoniae testing) 2. Further review of the laboratory's IQCP documents revealed the laboratory did not include the in-house QC data to support the reduction of performing QC to that of the manufacturer requirement of monthly quality control. 3. In interview on April 5, 2019 at 2:36 pm, the Technical Consultant confirmed the laboratory did not perform thirty (30) consecutive days of in house data to support the reduction of frequency in QC. 4. Review of the laboratory's Task 1 & 3 forms revealed the laboratory performs the following test volumes annually: a) Chlamydia - 50 tests b) Neisseria Gonorrhoeae - 50 tests c) Trichomonas Vaginalis - 50 tests d) Biofire FilmArray Respiratory Panel - 175 tests

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory followed the corrective action plan for proficiency testing results per the laboratory's policy. Refer to D6019. 2. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 3. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed

when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for proficiency testing results per the laboratory's policy. Findings: 1. The laboratory failed to attain a score of at least 80% for the Red Blood Cell and Hematocrit testing. Refer to D2121. 2. The laboratory failed to attain a satisfactory score score of at least 80% for Hematology in Event 3 of 2018. Refer to D2122. 3. The laboratory failed to achieve a score of at least 80% for Red Blood Cells in two of three consecutive events resulting in initial unsuccessful participation. Refer to D2130.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5445.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5403.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	<p>This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036. 1. The Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042.</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D5403.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.</p>