Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1023920	10/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Winnsboro Medical Clinic	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 October 13, 2021. 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on observation during the laboratory tour and review of proficiency testing (PT) results from the CASPER 155D report, the laboratory failed to successfully participate in proficiency testing for Chemistry. Findings: 1. The laboratory failed to

	achieve a score of at least 80% for Sodium (NA) in two out of three consecutive testing events, resulting in an initial unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour and review of proficiency testing results from the CASPER 155D report, the laboratory failed to achieve a score of at least 80% for Sodium (NA) in two out of three consecutive testing events, resulting in an initial unsuccessful performance. Findings: 1. Direct observation during the laboratory tour on October 13, 2021 at 9:30 am revealed the laboratory utilizes the Beckman Coulter AU480 Chemistry analyzer for Sodium (NA) testing. 2. Review of the CASPER 155D report proficiency test results for Sodium (NA) revealed the laboratory received the following scores resulting in an initial unsuccessful performance: a) 2021 1st Event NA score received 0% b) 2021 3rd Event NA score received 0%
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of installation records, test menu, and interview with personnel, the laboratory failed to have complete performance verification studies for the Abbott Ruby Cell-Dyn Emerald 22 Hematology analyer. Findings: 1. Observation by surveyor during the laboratory tour on October 13, 2021 at 10:37 am revealed the laboratory utilizes the Abbott Ruby Cell-Dyn Emerald 22 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's installation records for the Ruby Cell-Dyn Emerald 22 Hematology analyzer revealed the laboratory started patient testing on May 28, 2021. 3. Review of the summary page in the installation records revealed the laboratory performed the performance verification with raw data to support the studies for the following: a) Accuracy: method comparison b) Precision: Day-to-Day, Run-to-Run, and Within Run c) Reporatable Range: Linearity d) Reference Range 4. Further review of the installation records revealed the laboratory did not have the raw data to support complete precision for operator variance. 5. In interview on October 13, 2021 at 12:07 pm, the Technical Consultant stated that multiple operators participated in the studies but no raw data or signatures were included in the installation binder. 6. Review of the laboratory's test menu revealed the laboratory performs 4,000 CBC test annually.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of maintenance logs, and interview with personnel, the laboratory failed to ensure quarterly maintenance for the Beckman Coulter AU480 instrument was performed as required from January 1, 2021 through October 13, 2021. Findings: 1. Observation by surveyor during the laboratory tour on October 13, 2021 at 9:30 am revealed the laboratory utilizes the Beckman Coulter AU 480 instrument for Chemistry testing. 2. Review of the laboratory's "AU480 Maintenance Schedule" revealed the following quarterly maintenance tasks: a) Quarterly Maintenance *Clean the Air Filters *Replace the Detergent Rolling Tube 3. Further review of the "AU480 Maintenance Schedule" log revealed the quarterly maintenance tasks was to be performed during the following months in 2021 but the laboratory did not have documentation to support performance: a) January 2021 b) April 2021 c) July 2021 d) October 2021 4. In interview on October 13, 2021 at 12:40 pm, the Technical Consultant stated the maintenance was most likely performed and documented in the instrument but was not checked off the maintenance log. II. Based on observation by surveyor, review of maintenance logs, and interview with personnel, the laboratory failed to ensure three (3) of four (4) semi-annual maintenance tasks for the Abbott Ruby Cell-Dyn Emerald 22 instrument was performed as required for 2020 and 2021. Findings: 1. Observation by surveyor during the laboratory tour on October 13, 2021 at 9:30 am revealed the laboratory utilizes the Abbott Ruby Cell-Dyn Emerald 22 instrument for Hematology testing. 2. Review of the laboratory's "Cell-Dyn Emerald Maintenance Log" revealed the following semi-annual maintenance tasks: a) Semi-annual *Lubicate the Pistons 3. Further review of the "Cell-Dyn Emerald Maintenance Log" revealed the laboratory did not document the semi-annual maintenance tasks were to be performed for the following months in 2020 and 2021: a) March 2020 b) August 2020 c) August 2021 4. In interview on October 13, 2021 at 1:17 pm, the Technical Consultant stated the maintenance was performed but not documented by testing personnel on the maintenance log.
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 observation by surveyor, review of the laboratory studies and quality control

	records as well as interview with personnel, the laboratory failed to have in-house data to support the reduction in frequency of quality control (QC) for the Biofire Filmarray Torch analyzer. Findings: 1. Observation by surveyor during the laboratory tour on October 13, 2021 at 9:30 am revealed the laboratory utilizes the BioFire Filmarray Torch analyzer along with the Zeptometrix Natrol Respiratory Panel 2.1 quality control material for virology testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the laboratory reduced the frequency of QC to every thirty (30) days or with new lot/shipment. 3. Further review of the laboratory's IQCP and quality control records revealed the laboratory did not have the data to support reduction of the QC data prior to patient testing. 4. In interview on October 13, 2021 at 4:00 pm, the Technical Consultant stated the laboratory performed quality control every 30 days since the start of patient testing in December 2020 but due to QC supply shortages the laboratory was unable to perform quality control as required to reduce frequency. The Technical Consultant confirmed the IQCP was not complete.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of quality control records, manufacturer's quality control package inserts and interview with personnel, the laboratory failed to establish its own expected range of responses for the Zeptometrix quality control (QC) material. Findings: 1. Observation by surveyor during the laboratory tour on October 13, 2021 at 9:30 am revealed the laboratory utilizes the following analyzers and quality control (QC) material for virology testing: a) BioFire Filmarray Torch analyzer with Zeptometrix NaTrol Respiratory Panel 2.1 (RP2.1) quality control b) Cepheid GeneXpert analyzer with Zeptometrix Natrol SARS-Related Coronovirus 2 (SARS-CoV-2) External Run Controls c) Cepheid GeneXpert analyzer with Zeptometrix Natrol FLU/RSV/SARS-CoV-2 External Run Controls 2. Review of the manufacturer's quality control package inserts under "Expected Results" revealed the following statement: a) Zeptometrix NaTrol Respiratory Panel 2.1 (RP2.1) quality control: "Each Laboratory must evaluate the product and establish their own acceptance criteria" b) Zeptometrix NaTrol SARS-Related Coronovirus 2 (SARS-CoV-2) External Run Control: "Each Laboratory must evaluate the product and establish their own acceptance criteria" c) Zeptometrix Natrol FLU/RSV/SARS-CoV-2 External Run Control: "Each Laboratory must evaluate the product and establish their own acceptance criteria" 3. Review of the laboratory's quality control records revealed the laboratory did not establish their own range of acceptance criteria for each of the Zeptometrix NaTrol QC materials in use: a) Zeptometrix NaTrol

	Respiratory Panel 2.1 (RP2.1) quality control: no QC material in stock at time of survey b) Zeptometrix NaTrol SARS-Related Coronovirus 2 (SARS-CoV-2) External Run Control: Lot 325642 Expiration 12/30/21 c) Zeptometrix Natrol FLU/RSV/SARS-CoV-2 External Run Control: Positive control Lot 325902 Expiration 3/9/22 d) Zeptometrix Natrol FLU/RSV/SARS-CoV-2 External Run Control: Negative control Lot 325574 Expiration 2/11/22 4. In interview on October 13, 2021 at 3:30 pm, the Technical Consultant stated she was unaware that this QC material should be established. The Technical Consultant confirmed the laboratory uses the responses provided by the manufacturer and does not establish their own.
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 during the laboratory tour and review of the CASPER 155D report for proficiency testing, the Laboratory Director failed to provide overall management and direction for the laboratory. Refer to D6016.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour and review of proficiency

	testing CASPER 155D reports, the laboratory failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to achieve a score of at least 80% for Sodium (NA) in two out of three consecutive testing events, resulting in an initial unsuccessful performance. Refer to D2096.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure quality laboratory services were provided. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for the Biofire Filmarray Torch analyzer. Refer to D5445. 2. The laboratory failed to establish its own expected range of responses for the Zeptometrix quality control (QC) material. Refer to D5469.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.