Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0506716	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ochiltree General Hospital	3101 Garrett Dr, Perryton, TX	
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Review of manufacturer's instructions, patient final reports and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the Sofia SARS Antigen and the Sofia Flu+SARS Antigen test kits. The findings included: 1. Review of the manufacturer's instructions found on page 19 under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using the Sofia SARS Antigen FIA and the Flu+SARS Antigen FIA must include with the test result reports, all authorized Fact Sheets." 2. Review of patient results found no fact sheets included with the final report for three of three patient reports reviewed. 3. Interview of Testing Person one on the CMS report 209 Laboratory Personnel Report conducted August 19, 2021 at 10:50 AM confirmed that the authorized Fact Sheets were not provided to healthcare providers or patients with test results for SARS COV-2 testing.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by:

	Review of policies and procedures, proficiency testing records and interview of facility personnel found the laboratory failed to ensure that three of three testing personnel who routinely tested patient specimens for Arterial blood gasses participated in testing proficiency specimens in 2019, 2020 and 2021 (three testing events per year). The findings included: 1. Review of the policy titled Proficiency Testing Program found on page "All Proficiency Testing specimens will be treated the same as patient samples to include the following: a. They should be included in the normal analysis workload. b. They should be tested by routine personnel who normally in the A.B.G. lab using routine methods." 2. Review of the American Proficiency I institute (API) proficiency testing records for 2019, 2020 and 2021 found seven of seven testing events between 2019 1st event and 2021 1st event were tested by the same testing person (no longer employed). 3. Interview of testing person eight conducted on August 18, 2021 at 3:12 PM confirmed that the previous respiratory manager tested all of the proficiency samples in each of the proficiency testing events.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Review of the CMS report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that the laboratory failed to have procedures for performing competency assessments on all supervisors, consultants and testing personnel. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE 08/2017 INSPECTION Findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found the laboratory identified one general supervisor. 2. Review of personnel records found no competency assessments available for review for the general supervisor. 3. Interview of the general supervisor conducted on August 18, 2021 at 10:50 AM confirmed that there were no competency assessments for the general supervisor of the laboratory.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Review of Hematology proficiency testing records, Proficiency testing agency instructions and interview of facility personnel found the laboratory failed to evaluate results not scored by the proficiency testing agency in one of two testing events in 2021. THIS IS A REPEAT DEFICIENCY The findings included: 1. Review of the American Proficiency Institute (API) Hematology proficiency testing records for 2021 found the laboratory failed to evaluate results not graded by the proficiency testing agency in the 2021 Hematology/ Coagulation -1st Event as follows: a. Comment documented under corrective action on the Performance Review (Reviewed by Laboratory Director 5/6/21) "None needed all results 100%" b. Page 2 Educational

	Blood Cell Identification - 12 of 12 analytes were documented as Not Graded (6 Educational Sample) under the Performance column of the Comparative Evaluation. c. Page 3 Advanced Blood Cell ID - Seven of Seven specimens were documented as Not Graded (6 Educational Sample) under the Performance column of the Comparative Evaluation. d. Page 3 Automated Urine Microscopy -1 Sample UMI-01 result was Not Graded (2- No Consensus) for non- Squamous Epi (Iris- Quan) under the Performance column of the Comparative Evaluation. e. Page 3 Hematology - Nucleated RBC's specimen COU-02 result was Not Graded (3 See Data Summary) under the Performance column of the Comparative Evaluation. 2. Review of the Proficiency testing agency instructions to laboratories found on page 18 of the Users Guide -" Whenever a result is not graded, you should perform a self-evaluation. To do this, you would compare your result to the expected result(s). If your result falls within the expected range, you may conclude that your lab obtained the correct response. If your result does not fall within the expected range, you may want to troubleshoot to determine the cause. In most cases, the expected result is printed on your evaluation next to your reported result for each sample. If the expected result is not printed on your evaluation, to find the result or range of results that is the most appropriate for you to use for comparison: On the API website, click "Participant Data Summaries," located on the left-hand side of the screen. Choose the appropriate test event. You will see three drop-down menus, which will allow you to select the analyte, the peer group, and sample number. The Participant Data Summary includes descriptions of qualitative analytes (such as blood cell identification or organisms contained in culture samples) and other information that may help you with your documentation." 3. Interview of the General Supervisor on August 18, 2021 at 11:01 AM confirmed the laboratory did not evaluate results that were not graded by the proficiency testing agency in this event.
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: A. Observations, review of laboratory records, patient test records and interview of facility personnel found the laboratory failed to verify the performance of the miniiSED red blood cell sedimentation rate analyzer prior to testing 234 patient specimens. The findings included: 1. Observations made during a tour of the laboratory found the laboratory was using the miniiSED red blood cell sedimentation rate analyzer (serial number 00477 installed 07/01/2020) to test patient specimens. 2. Review of laboratory records found no documentation of verification studies for the miniiSED available for review to ensure the laboratory had verified the accuracy, precision, reportable ranges and that reference intervals were appropriate for the patient population. 3. Review of patient test records found the laboratory had tested 234 patient specimens using the miniiSED red blood cell sedimentation rate analyzer between 07/01/2020 and August 19, 2021 without verifying the performance of the analyzer. 4. Interview of testing person one conducted August 19, 2021 at 3:12 PM

	confirmed there were no verification studies available for review. B. Observations, review of laboratory records, patient test records and interview of facility personnel found the laboratory failed to verify the performance of the BD BACTEC FX 40 Blood Culture System prior to testing 146 patient specimens. The findings included: 1. Observations made during a tour of the laboratory found the laboratory was using the BD BACTEC FX 40 Blood Culture System (serial number FF 6025 installed 12/16/2020) to test patient specimens. 2. Review of laboratory records found no documentation of verification studies for the miniiSED available for review to ensure the laboratory had verified the accuracy, precision, reportable ranges and that reference intervals were appropriate for the patient population. 3. Review of patient test records found the laboratory had tested 234 patient specimens using the BD BACTEC FX 40 Blood Culture System between 12/16/2020 and August 19, 2021 without verifying the performance of the analyzer. 4. Interview of testing person one conducted August 19, 2021 at 3:47 PM confirmed there were no verification studies available for review. C. Observations, review of laboratory records and interview of facility personnel found the laboratory failed to verify the performance of the ABL Flex 80 Blood Gas analyzer prior to testing patient specimens. The findings included: 1. Observations made during the tour of the facility found the laboratory was using the ABL80 Flex blood Gas analyzer serial number 318124 installed July 1, 2020) to test patient specimens for arterial blood gasses. 2. Review of laboratory records found the laboratory failed to have documentation to verify the accuracy, precision, reportable range and reference ranges were appropriate for the patients tested using the blood gas analyzer. 3. Interview of testing person eight on the CMS Laboratory Personnel report conducted August 18, 2021 at 3:40 PM confined that he did not have any additional documentation to provide for verification of the analyzer. He went on to say he" just took over this position".
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Review of the laboratory's written policy, calibration verification records from 2020

	and 2021 and interview of facility personnel, it was found that the laboratory failed to have documentation of performing calibration verification for pH, PCO2 and PO2 tested on the ABL 80 FLEX Blood Gas Analysis System at least once every six months after installation July 1, 2020. Findings included: 1. Review of the laboratory's own policy titled ABL 80 FLEX found under the heading Q6 MONTH CALIBRATION VERIFICATION " Radiometer provides an additional manual fluid type for calibration verification. Range+QUALICHECK which is to be performed every 6 months or more often if needed. 2. Review of the laboratory's Calibration Verification records for 2020 and 2021 found calibration performed upon installation (07/01/2020) with no calibration verification procedures available for review. 2. Interview of testing person 8 conducted August 18,2021 at 4:08 PM confirmed that the laboratory failed to perform the calibration verification procedures on the the ABL 80 FLEX blood gas analysis system at least once every 6 months as directed in their own procedure.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of policies and procedures and interview facility personnel found that the quality control procedure available to testing personnel for the performance and assessment of quality control procedures for the ABL 80 FLEX blood gas analyzer failed to define a means of monitoring over time the accuracy and precision of test performance. THIS IS A REPEAT DEFICIENCY FROM THE MAY 2019 INSPECTION The findings included: 1. Review of the policy titled ABL 80 FLEX found" Quality control solutions will be ran at Ochiltree General Hospital Respiratory Department each day of patient testing 3 levels low, normal, and high. Additional quality control should be run after any troubleshooting or preventive maintenance which might alter the performance and whenever the technician has questions about the performance of the analyzer. All quality control values must pass before patient results can be released." 2. Review of quality control records found that the laboratory printed instrument reports and placed in the notebook for retention. There was no means of monitoring the performance of the control material over time. 3. Interview of testing person 8 conducted on August 18, 2021 at 4:10 PM confirmed that the laboratory did not use a Levy Jennings graphs or some other means to monitor over time the accuracy and precision of test performance. He stated that "if they did, Tony would have it".
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observations, review of the manufacturer's instructions for use, blood culture records, and interview of facility personnel, the laboratory failed to check each batch of media for, sterility, its ability to support and or inhibit growth and document the physical characteristics , for BD BACTEC Peds Plus/F Medium, BD BACTEC Lytic 10 Anaerobic/F Culture Media and BD BACTEC Plus Aerobic/F media used to test 146 patient specimens between December 16, 2020 and August 19, 2021. The findings included: 1. Observations made during the tour of the laboratory found the laboratory was using the BACTEC FX$) Blood culture System (serial number FF 6025 installed 12/16/2020) to test patient specimens. 2. Review of the manufacturer's instructions found under the heading QUALITY CONTROL: "Quality control requirements must be performed in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures." 3. Review of the Blood Culture Book provided found no documentation of quality control procedures (under the QC TAB of the notebook) for each of the three blood culture medium used. 3. Review of patient records between December 16, 2020 and August 19, 2021 found 146 patient specimens had been tested using the various media as described above. 4. Interview of testing person one on the CMS Report 209 Laboratory Personnel Report conducted August 19, 2021 at 5:03 PM found that the laboratory had historically accepted the manufacturer's quality control certificate and had not performed end user quality control procedures for blood culture media and does not document the condition of the media upon receipt.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of Blood Culture records and interview with facility personnel, the laboratory failed to perform gram stain quality control at least once each week of use when gram stain procedures were performed following positive blood culture identification for five of five patient samples. The findings included: 1. Based on review of patient blood culture records, the laboratory performed gram stains on five of five patient specimens with positive blood cultures. 2. Based on review of patient testing records, there was no documentation of gram stain controls being performed. 3. Interview of testing person one on August 19, 2021 at 4: 47 PM confirmed there was no documentation of gram stain quality control procedures being performed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, the laboratory's personnel files and staff interview it was revealed the technical supervisor failed to have documentation of performing semiannual competency assessments for four of seven testing personnel performing moderately complex testing during their first year of employment. THIS IS A REPEAT DEFICIENCY The findings were: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identified seven testing personnel performing moderate complexity testing. 2. Review of the laboratory's personnel files revealed the following testing personnel who were employed by the laboratory for over a year for which the laboratory failed to have documentation of semiannual competency assessments during the first year of employment for testing personnel four five six and ten: a. Testing person four (hire date 12/7/2020) one of one expected semiannual competency assessment not performed. b. Testing person five (hire date 01/07/2020) two of two semiannual competency assessments not performed. c. Testing Person six (hire date 09/01/2021) two of two semiannual competency assessments not performed. d. Testing person ten (hire date 12/10/2019) two of two semiannual competency assessments not performed. 3 . An interview with general supervisor listed on Form CMS 209 conducted August 18, 2021 at 11:07 AM confirmed the technical supervisor failed to perform semiannual competency assessments of testing personnel performing moderate complexity testing during their first year of employment.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, the laboratory's personnel files and staff interview it was revealed the technical consultant failed to have documentation of performing annual competency assessments for three of ten testing personnel performing moderately complex testing in 2019 and 2020. THIS IS A REPEAT DEFICIENCY The findings were: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identified ten testing personnel performing moderate complexity testing. 2. Review of the laboratory's personnel files revealed the following testing personnel who were employed by the laboratory for over a year for which the laboratory failed to have documentation of annual competency assessments during the first year of employment for testing personnel one, two, three: a. Testing person one (hire date 04/03/2017) no documentation of competency assessments performed in 2019 and 2020 b. Testing person two (hire date 04/06/2009) no documentation of competency assessments performed in 2019 and 2020 c. Testing Person three (hire date 08/19/2016) no documentation of competency assessment performed in 2019 3 . An interview with general supervisor

	listed on Form CMS 209 conducted August 18, 2021 at 11:07 AM confirmed the technical consultant failed to perform semiannual competency assessments of testing personnel performing moderate complexity testing at least annually in 2019 and 2020.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility found the laboratory failed to have documented training for one of ten testing personnel performing non waived testing. THIS IS A REPEAT DEFICIENCY FROM THE 08/2017 INSPECTION The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identified ten testing personnel performing non waived testing. 2. Review of personnel files found no documented training available for review for testing person ten (hire date 12 /10/2019). 3. Interview of the General Supervisor conducted August 18, 2021 at 10:50 AM confirmed he had no documented training for testing person ten. He went on to say that he "just never got it completed , but I do test."
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, the laboratory's personnel files and staff interview it was revealed the technical supervisor failed to have documentation of performing semiannual competency assessments for four of seven testing personnel performing high complexity testing during their first year of employment. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identified seven testing personnel performing high complexity testing. 2. Review of the laboratory's personnel files revealed the following testing personnel who were employed by the laboratory for over a year for which the laboratory failed to have documentation of semiannual competency assessments during the first year of employment for testing personnel four five six and ten: a. Testing person four (hire date 12/7/2020) one of one expected semiannual competency assessment not performed. b. Testing person five (hire date 01/07/2020) two of two semiannual competency assessments not performed. c. Testing Person six (hire date 09/01/2021) two of two semiannual competency assessments not performed. d. Testing person ten (hire date 12/10/2019) two of two semiannual competency assessments not performed. 3 . An interview with general supervisor listed on Form CMS 209 conducted August 18, 2021 confirmed the technical supervisor failed to perform semiannual competency assessments of testing personnel performing high complexity testing during their first year of employment.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, the laboratory's personnel files and staff interview it was revealed the technical supervisor failed to have documentation of performing annual competency assessments for three of ten testing personnel performing high complexity testing in 2019 and 2020. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identifiedseven testing personnel performing high complexity testing. 2. Review of the laboratory's personnel files revealed the following testing personnel who were employed by the laboratory for over a year for which the laboratory failed to have documentation of annual competency assessments during the first year of employment for testing personnel one, two, three: a. Testing person one (hire date 04/03/2017) no documentation of competency assessments performed in 2019 and 2020 b. Testing person two (hire date 04/06/2009) no documentation of competency assessments performed in 2019 and 2020 c. Testing Person three (hire date 08/19/2016) no documentation of competency assessment performed in 2019 3 . An interview with general supervisor listed on Form CMS 209 conducted August 18, 2021 at 11:07 AM confirmed the technical supervisor failed to perform semiannual competency assessments of testing personnel performing moderate complexity testing at least annually in 2019 and 2020.