Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0313254	09/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Haywood County Community Hospital, Inc	2545 North Washington Ave, Brownsville, 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
D0000	During a recertification survey that was completed on 09/22/23, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1240 Preanalytic systems
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package insert, the patient test report comment, the laboratory's proficiency testing records, the Centers for Medicare and Medicaid Casper Report 0155D (CMS 155), and interview with the laboratory supervisor, the laboratory failed to ensure the proficiency testing results for the non-waived direct antigen test for Respiratory Syntial Virus (RSV) was reported to Centers for Medicare and Medicaid Services (CMS) for 2023 event one and 2023 event two. The findings include: 1. Observation of the laboratory on 09/18/23 at 8:30 am revealed the Quidel Sophia RSV test in use for patient testing. 2. Review of the manufacturer package insert for the Quidel Sophia RSV revealed the following: "The Sophia RSV FIA employs immunofluorescence for detection of respiratory Syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly form symptomatic patients." The test is moderately complex when performed on patients from the age of seven to less than nineteen years of age. 3. Review of the patient test report comment revealed the following: "This test is intended for use with symptomatic pediatric patients under 19 years of age." 4. Review of the laboratory's proficiency testing records revealed the laboratory reported the non-waived Quidel Sophia RSV test to their PT provider as a

	waived test for 2023 event one and 2023 event two. 5. Review of the laboratory's CMS 155 report revealed no scores were reported to CMS for virology. 6. Interview with the laboratory supervisor on 09/19/23 at 4:30 pm confirmed the laboratory failed to ensure the non-waived RSV proficiency testing results were reported to CMS in 2023.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with the lab supervisor, the laboratory director failed to sign two of seven PT attestation statements reviewed for 2023. The findings include: 1. Review of the laboratory's proficiency testing records revealed that the attestation statement was not signed by the lab director for two of seven events reviewed (2023 event one for microbiology, 2023 event two for chemistry). 2. Interview with the lab supervisor on 09/19/23 at 4:30 pm confirmed the lab director had not signed the PT attestation statements for two of seven PT events in 2023.
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: Based on review of the laboratory procedure manual, the testing personnel competency assessment forms, and interview with the general supervisor, the forms used by the laboratory for assessing testing personnel competency were not in compliance with laboratory policy in 2023. The findings include: 1. Review of the laboratory's testing personnel competency evaluation policy revealed that "Recording /Reporting of Results" would be included as part of assessing competency. 2. Review of the forms used for assessing testing personnel competency revealed that recording and reporting of test results was not included as part of the competency assessment evaluation. 3. Interview with the general supervisor on 09/19/23 at 4:00 pm confirmed the forms used for performing and recording competency assessment did not include the required element of recording and reporting of test results for any of the test systems in use.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of patient test reports, the laboratory's proficiency testing policy, proficiency testing records and interview with the lab supervisor, the laboratory failed to ensure it followed its' own policy for participation in proficiency testing for the Ammonia and Fibrin Degradation Product (D-Dimer) analyte in 2023, with no corrective action performed. The findings include: 1. Review of the laboratory's test menu revealed the laboratory performs patient testing for Ammonia and D-Dimer. 2. Review of patient test reports revealed the first patient test for ammonia was performed on 02/09/23 (patient ID 500289); the first patient test for D-Dimer was performed on 05/28/23 (patient 502468). 3. Review of the laboratory's policy titled "Proficiency Survey Process" revealed the following statement: "The laboratory shall participate in external proficiency testing for each specialty and subspecialty of testing performed as a required form of testing accuracy validation." 4. Review of the laboratory's proficiency testing records revealed the laboratory had not performed and was not enrolled in proficiency testing for the ammonia and D-Dimer analytes. 5. Interview with the lab supervisor on 09/19/23 at 4: 30 pm confirmed the laboratory failed to follow its' own policy for participation in proficiency testing for the Ammonia and D-Dimer analytes in 2023, with no corrective action performed.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, staff interview and email communication, the laboratory failed to follow procedures for special handling of ammonia and lactic acid patient specimens (Refer to D5311).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, interview with the general supervisor, and email communication, the laboratory failed to follow procedures for special handling of ammonia and lactic acid patient samples,

	with a total of eleven ammonia tests performed and a total of ninety-one lactic acid tests performed since patient testing began in 2023. The findings include: 1. Observation of the laboratory on 09/18/23 revealed the Beckman Coulter AU chemistry instrument in use for patient testing for ammonia and lactic acid. 2. Review of the laboratory's procedure manual revealed the following: The procedure for ammonia under the section for Specimen Collection and Handling stated the following: "Centrifuge (cold) the sample to separate the plasma and store on ice until analysis. Heparin plasma must be tested immediately after processing." The procedure for lactic acid under the section for Specimen Collection and Preparation stated the following: "Keep the sample on ice and separate plasma from cells within 15 minutes of collection. Analyze the sample immediately." 3. During an interview with the general supervisor on 09/19/23 at 10:00 am, the supervisor was asked to describe how samples for ammonia and lactic acid are collected. The supervisor stated they are collected like any other sample. The laboratory does not use any special processes for sample handling or processing. This confirmed the survey findings. 4. Email communication received on 09/22/23 at 12:36 pm revealed the laboratory had performed a total of eleven ammonia tests and ninety-one lactic acid tests since patient testing began in 2023.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, the Individualized Quality Control Plan (IQCP) for the MedTox urine drug screen instrument, interview with the lab supervisor, and email communication, the laboratory failed to follow the procedure for conducting and implementing an IQCP for the MedTox urine drug screen with patient testing authorized on 04/13/23 with 62 patients reported since testing began. The findings include: 1. Observation of the laboratory on 09/8/23 at 8:30 am revealed the MedTox urine drug screen instrument in use for performing patient testing for qualitative urine drug screen. 2. Review of the laboratory policy titled "Laboratory Quality Control" revealed the following related to IQCP: The elements consist of a Risk Assessment, Quality Control Plan, Quality Assessment. The risk assessment is done by the lab in its' own environment by its' own testing personnel and must include all phases of testing and five components to include specimen, environment, reagent, test system and testing personnel. Must include a quality control plan and procedures and a quality assessment plan as well as annual assessment of the IQCP to determine if it continues to be appropriate for the system. 3. Review of the IQCP for the MedTox instrument revealed that a risk assessment was not performed and there was no quality control plan included as part of the IQCP. The test was authorized for patient testing beginning 04/13/23. 4. Interview with the lab supervisor on 09/19/23 at 4:00 pm confirmed the laboratory failed to follow its' own procedures for conducting and implementing an IQCP for the MedTox instrument. 5. Review of an email communication received on 10/02/23 at 1: 48 pm revealed the laboratory had tested a total of 62 patients since beginning testing on the MedTox urine drug screen instrument.

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 of the laboratory, review of test validation records, patient test results and staff interview, the laboratory failed to verify the normal/reference range for serum pregnancy test and serum ketone, and failed to verify the manufacturer reportable range for the Fibrin Degradation Product (D-Dimer) prior to patient testing in 2023. The findings include: 1. Observation of the laboratory on 09/18/23 at 8:30 am revealed the following non-waived test systems in use for patient testing: Serum pregnancy testing-Cardinal Health Serum Ketone using Biorex K-CHECK Fibrin Degradation Product (D-Dimer) on the Sysmex CA 600 instrument 2. Review of test validation records revealed the following that had not been completed: Normal /reference range study was not performed for the serum pregnancy or the serum ketone. Reportable range study was not completed for the D-Dimer. 3. Review of patient test reports revealed patient reporting for serum pregnancy test beginning 03/30 /23 (501499-1st patient), serum ketone beginning 04/13/23 (500555-1st patient), and D-Dimer beginning 05/28/23 (502468-1st patient). 4. Interview with the lab supervisor on 09/19/23 at 4:30 pm confirmed the laboratory did not verify the normal /reference range for the serum pregnancy test and serum ketone test, and did not verify the reportable range for the D-Dimer assay prior to patient testing in 2023.