Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406017	09/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Centracare Paynesville	200 1st Street W, Paynesville, MN	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to approve all procedures in use by the laboratory in 2023. Findings are as follows: 1. The laboratory performed Urinalysis testing as confirmed by Testing Personnel 3 during a tour of the laboratory at 11:05 a.m. on 09 /11/24. 2. An Arkray Aution Eleven analyzer was observed as present and available for use during the tour. The laboratory performed automated urinalysis testing using this analyzer beginning on 07/31/23. 3. PV documentation for urinalysis testing on the Aution Eleven analyzer included an accuracy verification via method comparison. The accuracy verification was approved by the General Supervisor on 07/25/23. Precision, reportable range, and reference range PV documentation was not found. See D5421 4. Laboratory director approval of the Aution Eleven PV was not found. The laboratory was unable to provide this documentation upon request.. 5. In an interview at 10:55 a.m. on 09/12/24, the Technical Consultant confirmed the above finding. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure two of two benchtop Bacteriology reagents were not used for patient testing after the expiration date had been exceeded in 2024. Findings are as follows: 1. The laboratory performed Bacteriology Beta Lactamase and microbial identification and antibiotic susceptibility testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory beginning at 11:05 a.m. on 09/11/24. 2. The following testing materials were observed as present and available for use during the tour of the laboratory: 0.45% Sodium Chloride Inhalation Solution (saline) Lot ZI-2208122 expiration date 08/01/24 Sterile Water for Irrigation Lot number 32-610-48-02 expiration date 08/01/24 Cefinase Beta Lactamase detection discs Lot number 4004767 Expiration date 01/03/25 Vitek 2 microbial identification and antibiotic susceptibility analyzer 3. The laboratory used expired sterile water for two Beta Lactamase tests on patient specimens in the time period of 08/01/24 through 09 /11/24 as indicated by TP3 during the tour and confirmed in laboratory records. 4. The laboratory used expired saline for 127 microbial identification and antibiotic susceptibility tests on patient specimens using the Vitek 2 analyzer in the time period of 08/01/24 through 09/11/24 as indicated by TP1 at 11:20 a.m. on date of survey. This information was obtained from the laboratory information system. 5. In an interview at 11:10 a.m. on 09/11/24, TP3 confirmed the sterile water and sterile saline expiration dates had been exceeded. .
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, document review, and interview with laboratory personnel, the laboratory failed to complete required performance verification (PV) activities for one of one new analyzers implemented by the laboratory in 2023. Findings are as follows: 1. The laboratory performed Urinalysis testing as confirmed by Testing Personnel 3 during a tour of the laboratory at 11:05 a.m. on 09/11/24. 2. An Arkray Aution Eleven analyzer was observed as present and available for use during the tour. The laboratory performed an automated urinalysis test panel using this analyzer which included the following ten analytes: Glucose, Protein, Bilirubin, pH, Blood, Urobilinogen, Ketone, Nitrate, Leukocyte, Specific Gravity. 3. PV documentation for urinalysis testing on the Aution Eleven analyzer included an accuracy verification via method comparison. Precision, reportable range, and reference range PV documentation was not found. Laboratory director approval of the PV was not found. See D5407 The laboratory was unable to provide the missing documentation upon request. 4. In an interview at 10:55 a.m. on 09/12/24, the Technical Consultant confirmed the above finding. 5. In an email received at 10:42 a.m. on 09/19/24, the GS indicated urinalysis testing on the Aution Eleven analyzer was implemented on 07 /31/24 and the laboratory performed 2586 urinalysis tests in the time period of 07/31 /23 through 09/12/24. .