Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315053	10/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Conrad Pearson Clinic, The	3950 New Covington Pike, Suite 340, Memphis, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory's quality assessment process was ineffective when it failed to detect and correct problems with quality control limits and lot numbers in use for urine dipstick testing in 2017 and 2018. (Refer to D5293)
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality control (QC) records and the manufacturer package insert for urine dipstick controls, the laboratory's quality assessment documents, six patient test reports and interview with the laboratory liaison, the laboratory's quality assessment (QA) process was ineffective when it failed to detect and correct problems with quality control limits and lot numbers in use for urine dipstick testing in 2017 and 2018. The findings include: 1. Observation of the laboratory on October 4, 2018 at 12:35 pm revealed the

	Siemens Clinitek Advantus in use for moderate complex urine dipstick patient testing. 2. Review of the laboratory's QC records and the manufacturer package insert for urine dipstick controls revealed the following errors in levels one and two quality control limits and lot number documentation: February 2017 QC Lot 44221 Range in use Correct Range Specific Gravity 1.020-1.030 1.010 - >1.030 Creatinine 10-50 mg /dL 10-100 mg/dL QC Lot 44222 Range in use Correct Range Specific Gravity 1.005-1.020 1.005 - 1.025 Glucose 100-1000 mg/dL Trace - 1000 mg/dL Blood Tr-3+ 1+ - 3+ Protein Tr-300 mg/dL 30 - >300 mg/dL May 2017 Lot # recorded as 44021 Lot #=44221 Range in use Correct Range Specific Gravity 1.005-1.030 1.010 - >1.030 QC Lot 44222 Range in use Correct Range Specific gravity 1.005-1.020 1.005 - 1.025 Glucose 100-1000 mg/dL Trace - 1000 mg/dL Blood Tr-3+ 1+ - 3+ Protein Tr-300 mg /dL 30 - >300 mg/dL October 2017 QC Lot number in use not recorded February 2018 QC Lot 44301 Range in use Correct Range Specific Gravity 1.005 - 1.030 1.010 - >1.030 QC Lot 44302 Range in use Correct Range Specific Gravity 1.005 - 1.020 1.005 - 1.025 Glucose 100-1000 mg/dL Trace - 1000 mg/dL Blood Tr-3+ 1+ - 3+ Protein Tr-300 mg/dL 30 - >300 mg/dL June 2018 QC Lot 44511 Range in use Correct Range Specific Gravity 1.005 - 1.030 1.010 - >1.030 QC Lot 44512 Range in use Correct Range Specific Gravity 1.005-1.020 1.005 - 1.025 Glucose 100-1000 mg /dL Trace - 1000 mg/dL Blood Tr-3+ 1+ - 3+ Protein Tr-300 mg/dL 30 - >300 mg/dL October 2018 QC Lot 44471 Range in use Correct Range Specific Gravity 1.005 - 1.030 1.010 - >1.030 QC Lot 44472 Range in use Correct Range Specific Gravity 1.005-1.020 1.005 - 1.025 Glucose 100-1000 mg/dL Trace-1000 mg/dL Blood Tr-3+ 1+ - 3+ Protein Tr-300 mg/dL 30 - >300 mg/dL 3. Review of the laboratory's quality assessment documents for 2017 and 2018 revealed review of the monthly urine dipstick quality control records by the laboratory director/technical consultant with no corrective action identified and corrected for the incorrect quality control limits and lot numbers for the following: January to April 2017, May to August 2017, September to December 2017, January to March 2018, April to June 2018. 4. Review of six patient test reports revealed patient testing on dates 2.16.17, 5.1.17, 10.19.17, 2.1.18, 6.26.18, 10.04.18 respectively. 5. Interview with the laboratory liaison on October 4, 2018 at 3:00 pm confirmed the laboratory's QA process does not include review of correct quality control limits and lot numbers in use. The QA process was ineffective when it failed to detect and correct problems when incorrect quality control limits and lot numbers were in use in 2017 and 2018 with patient testing performed.