Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1037669	04/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Concentra Medical Centers	10452 Baltimore Avenue, Beltsville, MD	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory did not have an eyewash in the laboratory where the testing was being performed. Findings: 1. The laboratory is required to implement safety policies and procedures to ensure safety in the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. 2. The area where laboratory testing is performed was reviewed during the survey. Observation of the testing area showed that there was no eyewash attached to the sink to aid in flushing out the eyes of the testing personnel if they were to have been splashed with any chemicals. 2. During the survey on 04/24 /2018 at 1:30 PM the technical consultant confirmed that the an eyewash station was not in the area where the testing was being performed.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) procedure and interview with the technical consultant, the laboratory director did not ensure that the annual split sample QA procedure was being performed and documented each year as required to ensure the quality of laboratory services. Findings: 1. The QA procedure requires the laboratory to perform split samples annually. Review of the QA records show that the annual split sample testing had not been performed in 2017. 2. During the survey on 04 /24/18 at 1:30 PM the technical consultant confirmed that the laboratory was no longer performing annual split sample testing as part of the QA plan and had not update the QA plan to reflect this change.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, quality control (QC) records and interview with the technical consultant, the testing personnel did not follow the laboratory's procedures when preparing the monthly QC folders. Findings: 1. According to the "CBC Control Folders" procedure, "At the end of each testing month, a new folder will be prepared with a photocopy of the assay sheet placed inside the folder." The assay sheet contains the lot number, expiration date and reference ranges of the complete blood count (CBC) QC materials being used each month. 2. The QC materials are usually good for three months. Review of the QC folders for 2016 and 2017 showed that the QC assay sheet was only present in every third folder and not in every folder as required. 3. During the survey on 04/24/18 at 1:30 PM the technical consultant confirmed that the testing person was not attaching a photocopy of the QC assay sheet inside of the QC folder each month to show which lot was being used and to show that the QC material was not being used past the expiration date.