Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2193225	08/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Monarch Addiction Recovery Clinics, Sc	521 E Washington Ave, Madison, WI	

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
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: Item 1: Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory director did not review the performance specification verification records for chemistry on the Diatron Pictus 700 prior to reporting patient results. Findings include: 1. Review of the patient log revealed the laboratory performed chemistry patient testing on the Diatron Pictus 700 on October 19, 2020. 2. Review of the performance specification verification record for the Diatron Pictus 700 analyzer showed the laboratory director reviewed and accepted the chemistry performance specification verification on October 20, 2020. 3. Interview with the general supervisor on August 25, 2021 at 12:10 PM confirmed the laboratory director did not review and accept the performance specification verification for chemistry on the Diatron Pictus 700 analyzer prior to reporting patient results. Item 2: Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory director did not review the performance specification verification records for toxicology on the Diatron Pictus 700 prior to reporting patient results. Findings include: 1. Review of the patient log revealed the laboratory performed toxicology patient testing on the Diatron Pictus 700 on October 19, 2020. 2. Review of the performance specification verification record for the Diatron Pictus 700 analyzer showed no documentation that the laboratory director reviewed and accepted the

	toxicology performance specification verification. 3. Interview with the general supervisor on August 25, 2021 at 12:10 PM confirmed the laboratory director did not review and accept the performance specification verification for toxicology on the Diatron Pictus 700 analyzer prior to reporting patient results.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of testing personnel records and interview with the general supervisor, the laboratory director did not ensure one of one testing personnel received the appropriate training on the Diatron Pictus 700 and Sciex Triple Quad 4500 analyzers prior to testing patients' specimens. Findings include: 1. Review of the testing personnel records revealed no documentation of employee training on the Diatron Pictus 700 and Sciex Triple Quad 4500 analyzers. 2. Interview with the general supervisor on August 25, 2021 at 9:49 AM confirmed the laboratory director did not ensure one of one testing personnel received the appropriate training for the type and complexity of services offered prior to testing patients' specimens.