Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2147959	11/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Jb Pain Free Md Pllc Dba The York Pain Ctr	718 S Main St, Red Lion, PA	

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
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 laboratory procedure manuals and interview with technical supervisor (TS), the laboratory failed to establish a complete procedure to assess the competency of 1 of 1 TS competency in 2019. Findings Include: 1. On the day of survey, 11/20/2019, the laboratory failed to provide a complete written policy to assess the competency 1 of 1 TS competency in 2019. 2. The TS confirmed the finding above on 11/20/2019 around 09:00 am.
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 review of policies/ procedures and interview with the technical supervisor (TS), the laboratory failed to ensure policies/ procedures (19 out of 19) were approved, signed, and dated by the current laboratory director (LD) before use on 7/24 /2019. Findings Include: 1. On the day of survey, 11/20/2019, review of laboratory policies/ procedures (19 out of 19) revealed, the current LD (start date of 7/23/2019), did not approve, sign, and date laboratory procedures before patient testing began on 7 /24/2019. 2. The policies/ procedures were signed by the LD on the following dates: -

	15 out of 19 policies: 9/10/2019. - 1 out of 19 policies (Maintenance policy): 11/14 /2019. - 1 out of 19 policies (Carolina Liquid Chemistries 800 clinical Chemistry Analyzers policy): 11/18/2019. - 1 out of 19 policies (Quality Assessment policy): 11 /18/2019. - 1 out of 19 policies (Sample preparation Policy) was not signed by the LD 2. On 11/20/2019 around 10:30 am, the TS confirmed that the LD did not sign policies/ procedures before patient testing began on 7/24/2019.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory quality assurance procedure, quality assurance records and interview with technical supervisor (TS), the laboratory failed to ensure that quality assessment (QA) programs were documented and reviewed to assure the quality of laboratory from July 2019 to October 2019 (4 of 4 months). Findings Include: 1. On the day of survey, 11/20/2019, review of QA records revealed, the laboratory director (LD) did not sign monthly QA activities documented from July, August, September and October of 2019 (4 of 4 months) until 11/14/2019. 2. The TS confirmed the finding above on 11/20/2019 around 9:40 am.