Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0234293	10/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
H Richard Reynolds Md	2345 Chesterfield Avenue Suite 204, Charleston, WV	

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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory quality control (QC) records, patient testing logs, and an interview with the laboratory director (LD), the laboratory failed to (e)(4)(i) check each batch of media for sterility if sterility is required for testing, (e)(4)(ii) check each batch of media for its ability to support growth, and (g) document all control procedures performed. Findings: 1. A review of the laboratory DTM QC log and the patient testing log identified 3 new lots (184901, 1836902, 1833908) of DTM media, that no record of a sterility check or ability to support growth for QC could be located. 2. A review of the laboratory DTM QC log identified 4 new shipments of DTM media on 4/15/19, 5/15/19, 6/17/19, and 7/17/19. There were no lot numbers recorded for each of these shipments. No documentation of the lot numbers received on these dates, or the appropriate QC being performed, could be located. 3. An interview with the LD, on 10/1/19 at approximately 12:15 PM, confirmed the findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of the laboratory written policies and procedures, quality assurance (QA) records, and an interview with the laboratory director (LD), the laboratory failed to follow written policies and procedures for monitoring, assessment, and correction of problems identified in the post analytic system. Findings: 1. A review of the laboratory written policy "Quality Systems Assessment", states "every six months, (February and August of each year) the receptionist/medical assistant pulls ten patient charts.....Those charts (and their respective separate files) are reviewed thoroughly for completeness with respect to.." No documentation of this QA could be located in the 2018 and 2019 records. 2. An interview with the LD, on 10/1/19 at approximately 12: 15 PM, confirmed the findings.