Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2224771	03/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Encompass Laboratory Llc	2323 S Voss Rd, Unit 455, Houston, TX	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 3/27/23. Based on a review of the laboratory's policies, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to follow its policy by ensuring the no template control was negative prior to resulting three patient's Urinary Tract Infection Panel PCR tests on the BioRad CFX96 system on March 15, 2023. Findings include: 1. A review of the laboratory's policy titled 'Seegene Novaplex Urinary Tract Infection (UTI) Panels 1, 2, 3 PCR Test Validation' revealed the following: "Quality Control and Result Interpretation: - Known no-template control sample is included somewhere on the plate for each master mix used on the PCR plate. - All negative controls do not have C(t)s detected in all fluorescent channels across each of the data-capture steps." 2. A review of the laboratory's records revealed on March 15, 2023, the no template control was positive for UTI Panel 2 and the following 3 patient's tests were resulted: - Patient CK03081936 - Patient JG01301955 - Patient SM12191947 3. An interview with the technical consultant on 3/27/23 at 12:27 p.m. in the office, after review of the records, confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 3/22/23. Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory's quality assurance plan failed to identify and correct problems in analytic systems. Findings include: 1. The laboratory failed to have documentation of an accuracy and precision study for four Seegene Novaplex PCR panels tested on the BioRad CFX96 system. (Refer to D5423)