Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0546491	03/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Urology Medical Group	8631 W 3rd St Ste 1115e, Los Angeles, CA	

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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's Precision UTI, STI, vaginitis, and yeast organisms panels for the detection of bacterial and fungal organisms using the Polymerase Chain Reaction (PCR) test, and interviews with the laboratory testing personnel (TP) on March 26, 2021 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of multiple microbial agents using Precision microorganism's panels for molecular detection. 2. During the laboratory tour on 03/26/2021 at approximately 11: 30 a.m. the examiner observed that specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection were all performed in the same room-area. 3. The TS confirmed by interview on March 23, 2021 at approximately 11:40 a. m. that the laboratory's molecular PCR testing for the presumptive detection of UTI, STI, vaginitis and yeast organisms was not set up in separate rooms with unidirectional flow. 5. Based on laboratory records, the laboratory performed and reported approximately 2,546 molecular diagnostic tests since started testing by PCR on September 2020.
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: Based on the lack of laboratory written policies and procedures and interview with the General supervisor (GS) and testing personnel (TP), it was determined that the laboratory failed to establish and follow written procedures for the molecular section. The findings included: 1. On the day of the survey 03/26/2021 at approximately 11:30 a.m. the laboratory failed to provide written policies and procedures for the molecular testing section. 2. For three (3) out of eight (3) random patient test results reviewed covering period from January 11/20/2019 to 02/17/2021; UTI, STI, vaginitis, and Mycology panels for molecular detection of multiple micro-organisms were ordered, analyzed, and reported for which the laboratory had no policies and procedures written. 3. The GS and TP confirmed on 03/26/2021 at approximately 1:00 p.m. that the laboratory lacked established written policies and procedures for the molecular section.
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: Based on interview with the laboratory testing personnel (TP) on March 26, 2021 and review of laboratory records; it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the pre-analytic, analytic, and post-analytic phases of clinical testing for the molecular detection of organisms. The findings included: 1. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in all phases of testing for the Polymerase Chain Reaction (PCR) procedure prior to reporting patient test results. 2. The laboratory staff confirmed on 03/26/2021 at approximately 12:00 p.m. that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in all phases of PCR testing. 4. Based on the declaration of test volumes for the year 2020 submitted on 03/26/2021; the laboratory processed and reported 2,546 PCR test procedures
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

	This STANDARD is not met as evidenced by: Based on the lack of separate areas for specimen preparation, amplification and product detection, and reagent preparation (D3005), established policies and procedures for molecular testing (D5401), and failure to establish a Quality Assurance program for molecular testing from pre-analytic, analytic, and post-analytic phases of clinical testing (D5791); it was determined that the laboratory director failed to ensure that testing systems developed and used for each tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.