Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2119391	11/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Orange Toxicology Lab Inc	1535 South D St, Ste 210, San Bernardino, 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 detection of dermatomycosis of nails by the Polymerase Chain Reaction (PCR) testing, and interviews with the technical supervisor (TS) and the laboratory director (LD) on November 2, 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, DNA extraction, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of dermatomycosis in nails using the Multiplex PCR by Uroimmune test system. 2. During the laboratory tour on 11/2/2021 at approximately 1:30 p.m. the surveyor observed that specimen preparation, DNA extraction, preparation of reagents, and sample template addition were all performed in the same open area without unidirectional flow. 3. The TS and LD confirmed by interview on November 2, 2021 that the laboratory's molecular PCR testing for the presumptive detection of dermatomycosis in nails was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 2,000 Real Time PCR molecular diagnostic tests annually.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental

	conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyor's direct observations of the laboratory's detection of dermatomycosis in nails by PCR testing processes and interview with the laboratory's technical supervisor and laboraotry director on November 2, 2021; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed. Findings include: See D3005.