Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0646585	08/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Unilab, Inc	418 N Austin Blvd, Oak Park, IL	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CASPER Report 0155D and interview with a American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for the routine chemistry analytes calcium (total), cholesterol (total), creatine, and blood urea nitrogen (BUN) during PT events one and two of 2022. See D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of CASPER Report 0155D and interview with a American Proficiency Institute (API) representative; the laboratory failed to successfully participate in proficiency testing (PT) for the routine chemistry analytes calcium (total), cholesterol (total), creatine, and blood urea nitrogen (BUN) during PT events one and two of 2022. Findings include: 1. Review of the CASPER Report 0155D ran on 8-1-2022 identified the initial unsuccessful PT performance for the specialty of chemistry analytes: calcium (total), cholesterol (total), creatine, and blood urea nitrogen (BUN). ROUTINE CHEMISTRY Calcium, total - EVENT-1, 2022 = 0% - Unsatisfactory Calcium, total - EVENT-2, 2022 = 60% - Unsatisfactory Cholesterol, total - EVENT-1, 2022 = 20% - Unsatisfactory Cholesterol, total - EVENT-2, 2022 = 0% - Unsatisfactory Creatine - EVENT-1, 2022 = 60% - Unsatisfactory Creatine - EVENT-2, 2022 = 20% - Unsatisfactory BUN - EVENT-1, 2022 = 40% - Unsatisfactory BUN - EVENT-2, 2022 = 20% - Unsatisfactory 2. A phone interview with the API PT representative on 08/01/2022, at 9:55 AM, confirmed the unsuccessful PT performance for the analytes calcium (total), cholesterol (total), creatine, and blood urea nitrogen (BUN) in PTevents one and two of 2022.