

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0628395	(X3) Date Survey Completed 08/02/2022
Name of Provider or Supplier St Charles Madras Laboratory	Street Address, City, State 470 Ne A St, Madras, OR	
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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Proficiency Testing (PT) desk review of the College of American Pathologists (CAP) proficiency testing revealed the laboratory had unsuccessful participation for two consecutive testing events 3rd event 2021 and 2nd event 2022. for the analyte Urea Nitrogen (BUN). Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Proficiency Testing (PT) desk review of the College of American Pathologist (CAP) proficiency testing (PT) showed the laboratory had unsuccessful participation for the 3rd event 2021 and 2nd event of 2022 for the analyte Urea Nitrogen (BUN). Findings include: 1. 3rd event 2021 , Urea Nitrogen (BUN) = 0% 2. 2nd event 2022, Urea Nitrogen (BUN) = 60%