

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0625696	(X3) Date Survey Completed 12/03/2020
Name of Provider or Supplier Downtown Salem Primary Care Lab	Street Address, City, State 1234 Commercial Street Se, Salem, 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	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: Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing (PT) shows the laboratory had unsuccessful participation for the Analyte Human chronic gonadotropin (HCG) in Endocrinology. Refer to D2107.
D2107	ENDOCRINOLOGY CFR(s): 493.843(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:

Review of Proficiency testing shows the laboratory failed two consecutive testing events for the analyte Human chorionic gonadotropin (HCG). Findings include: 1. 2nd Event 2020 - HCG = 0% 2. 3rd Event 2020 - HCG = 0%