

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2114201	(X3) Date Survey Completed 01/28/2020
Name of Provider or Supplier Summit Clinical Laboratory, Llc	Street Address, City, State 17742 Preston Road #205, Dallas, TX	
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: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER reports 155 & 153 (CMS 153&155) and the PT agency, College of American Pathologist (CAP) evaluation report determined the laboratory failed to maintain satisfactory performance for the 2nd and 3rd event 2019 in Cholesterol-HDL (HDL) (Refer to D2096), in the subspecialty of Endocrinology for Cortisol and HCG (Refer to D2107) and in the subspecialty of Toxicology (Refer to D2118) for the following analytes: Carbamazepine (CARB), Digoxin (DIG),</p>

	<p>Ethosuximide, Gentamicin (GENT), Lithium, Phenobarbital (PHEN), Phenytoin, Primidone, Quinidine, Theophylline (THEO), Tobramycin, Valproic Acid (VALP) resulting in the first unsuccessful PT occurrence for 2020.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER reports 155 & 153 (CMS 153&155) and the PT agency, College of American Pathologist (CAP) evaluation report determined the laboratory failed to maintain satisfactory performance for the 2nd and 3rd event 2019 in the analyte Cholesterol-HDL (HDL) resulting in the first unsuccessful PT occurrence for 2020. The findings include: 1. Review of the CMS Casper 153 & 155D reports revealed a score of 0% for the 2nd and 3rd event 2019 for the analyte HDL. 2. Review of the CAP evaluation report revealed the laboratory failed to achieve successful performance for the 2nd and 3rd event 2019 with a score of 0% for the analyte HDL resulting in the first unsuccessful PT occurrence for 2020.</p>
<p>D2107</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER reports 155 & 153 (CMS 153&155) and the PT agency, College of American Pathologist (CAP) evaluation report determined the laboratory failed to maintain satisfactory performance in the subspecialty of Endocrinology for the 2nd and 3rd event 2019 for the analytes Cortisol and HCG resulting in the first unsuccessful occurrence for 2020. The findings include: 1. Review of the CMS Casper 153 & 155D reports revealed a score of 0% for the 2nd and 3rd event 2019 for the analytes Cortisol and HCG. 2. Review of CAP evaluation report revealed the laboratory failed to achieve successful performance for the 2nd and 3rd event 2019 with a score of 0% in the subspecialty of Endocrinology for the analytes Cortisol and HCG resulting in a first unsuccessful PT occurrence for 2020.</p>
<p>D2118</p>	<p>TOXICOLOGY CFR(s): 493.845(f)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER reports 155 & 153 (CMS 153&155) and the PT agency, College of American Pathologist (CAP) evaluation report determined the laboratory failed to maintain satisfactory performance in the subspecialty Toxicology for the 2nd and 3rd event 2019 in the following analytes: Carbamazepine (CARB), Digoxin (DIG), Ethosuximide, Gentamicin (GENT), Lithium, Phenobarbital (PHEN), Phenytoin, Primidone, Quinidine, Theophylline (THEO), Tobramycin, Valproic Acid (VALP) resulting in the first unsuccessful occurrence for 2020. The findings include:

1. Review of the CMS Casper 153 & 155D reports revealed a score of 0% for the 2nd and 3rd event 2019 in the following analytes: CARB, DIG, Ethosuximide, GENT, Lithium, PHEN, Phenytoin, Primidone, Quinidine, THEO, Tobramycin, VALP.
2. Review of CAP evaluation report revealed the laboratory failed to achieve successful performance for the 2nd and 3rd event 2019 with a score of 0% in the subspecialty Toxicology in the following analytes: CARB, DIG, Ethosuximide, GENT, Lithium, PHEN, Phenytoin, Primidone, Quinidine, THEO, Tobramycin, VALP resulting in a first unsuccessful PT occurrence for 2020.