

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2060724	<b>(X3) Date Survey Completed</b>  08/15/2019
<b>Name of Provider or Supplier</b>  Sbh Diagnostics Inc	<b>Street Address, City, State</b>  4 Strathmore Rd, Natick, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial CLIA certification survey was conducted for the SBH Diagnostics, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
<b>D5423</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish performance specifications for one (1) of one (1) newly implemented test systems not subject to FDA clearance as evidenced by the following: Beta Catenin and Actin ratio: Specificity a) A review of validation studies for the Beta Catenin and Actin ratio assay revealed that the laboratory failed to perform specificity studies as part of the validation. b) The laboratory director stated in an interview on 8/15/19 at 11:15 a.m. that he had performed a literature search of the assay and found that there was no interference from any other substances. However the results of this literature search was not included in the validation summary. c) The laboratory performs approximately 240 Beta Catenin and Actin ratio assays annually.</p>