Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2168718	01/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Nasoncare Llc	2233 Northwoods Blvd, Attn Pamela Brady, North Charleston, SC	

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: During an onsite initial survey performed on 01/31/2022, based on review of CASPER report 155D and graded reports from Medical Laboratory Evaluation (MLE) it was determined that the laboratory failed to successfully participate in proficiency testing for the specialty of hematology, the analyte platelet (PLT) for two consecutive proficiency testing events reviewed (2021, Events 2 and 3). See D2121 and D2130.
D2121	HEMATOLOGY CFR(s): 493.851(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: During an onsite initial survey performed on 01/31/2022, based on review of the CASPER report 155D and laboratory proficiency testing records (graded report from MLE), it was determined that the laboratory failed to attain a score of at least 80 percent in proficiency testing for the specialty of hematology, the analyte platelet for two consecutive proficiency testing events (2021, Events 2 and 3). The findings include: 1. Review of CASPER report 155D revealed the following Plt proficiency scores for your laboratory: a. 2021, Event 2: 0% b. 2021, Event 3: 60% 2. The scores were confirmed upon review of the graded MLE reports. Scores less than 80% for these analytes indicate failure or unsatisfactory performance. A failure of the analytes for two consecutive or two out of three testing events is scored as unsuccessful. A failure of the analyte for three consecutive or three out of four/five events is scored as a repeat unsuccessful.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: During the onsite initial survey performed on 01/31/2022, based on review of CASPER report 155D and graded MLE results, it was determined that the laboratory failed to achieve satisfactory performance for platelets in two consecutive testing events (2021, Events 2 and 3) resulting in unsuccessful proficiency testing performance. See D2121.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: During an onsite initial survey on 01/31/2022, based on procedure manual review and confirmation by testing personnel, the laboratory failed to establish and maintain a written policy on the description of the course of action to take if a test system becomes inoperable. Findings include: 1. Review of the laboratory procedure manual on 01/31/2022 revealed that there was no written policy on the description of the course of action to take if a test system becomes inoperable 2. Testing personnel confirmed during an onsite interview on 01/31/2022 at 1:30 pm that there was no written policy on the description of the course of action to take if a test system becomes inoperable.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: During an onsite initial survey on 01/31/2022, based on based on the Medonic operator's guide, laboratory calibration record review, and testing personnel interview, the laboratory failed to ensure that a routine calibration verification was performed on the analyzer at least every six months as required by the manufacturer for 2 of 3 years reviewed from 2020 to 2022 (2020 and 2021). Findings include: 1. The Medonic operator's guide stated that a calibration verification should be performed at least every six months. 2. Review of laboratory calibration records revealed that calibration verification was not performed or documented for 2 of 3 years reviewed from 2020 to 2022 (2020 and 2021). 3. Testing personnel confirmed during an onsite interview on 01/31/2022 at 1:30pm that the laboratory had failed to ensure that a routine calibration verification was performed on the analyzer at least every six months for 2 of 3 years reviewed from 2020 to 2022 (2020 and 2021).