

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2053864	(X3) Date Survey Completed 10/01/2018
Name of Provider or Supplier Northside Ent, Inc	Street Address, City, State 12065 Old Meridian St, Ste 205, Carmel, IN	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to have a policy /procedure and evaluate proficiency testing (P.T.) performance for one of one assay performed, Radioallergosorbent Test (RAST), twice annually in 2017. Findings include: 1. Review of twice annual verification for 2017 indicated only one evaluation for RAST testing occurred on 1/30/17 and no other evaluation had been performed for 2017. 2. Medical record review indicated the following patients had RAST testing performed in 2017 (112 tests performed annually): a. PT#5: 10-3-17, RAST=POS/SP-3 b. PT#6: 9-12-17, RAST=Neg (Neg=Negative)/SP-3 c. PT#7: 12-6-17, RAST=POS /SP-1 d. PT#8: 11-14-17, RAST=POS/SP-1 3. In interview on 10/01/18 at 1:15 PM, SP-1 confirmed twice annual verification for RAST testing only occurred once in 2017 (1/30/17) and there was no policy/procedure available for review.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:
 Based on observation, document review, and interview, the laboratory failed to perform maintenance including revolutions per minute (RPM) and timer checks for one of one centrifuge (serial #1505-13AG432), since 5/11/15. Findings include: 1. On 10/01/18 at 10:16 AM, a centrifuge (Horizon/Serial #1505-13AG432) was observed on the counter in the laboratory with a maintenance sticker indicating the last maintenance being performed on 5/11/15. 2. Review of policy/procedure titled, "S-5 Policy on Centrifuge Checks," no in use date nor laboratory director approval read, "It is the policy of Northside ENT that the revolutions per minute (RPMs) of the centrifuges are checked at least annually. In any testing area where the time of centrifugation is critical to the reliable production of accurate test results, the built-in timer will also be checked..." 3. Medical record review indicated the following patients were tested in the laboratory for RAST (112 tests annually), which requires the use of the centrifuge: a. PT#1: 7-6-18, RAST=POS (POS=Positive) b. PT#2: 6-6-18, RAST=POS c. PT#3: 5-3-18, RAST=POS d. PT#4: 4-4-18, RAST=POS e. PT#5: 10-3-17, RAST=POS f. PT#6: 9-12-17, RAST=Neg (Neg=Negative) g. PT#7: 12-6-17, RAST=POS h. PT#8: 11-14-17, RAST=POS 4. In interview on 10/01/18 at 10:17 AM, SP-1 confirmed there has been no maintenance since "2015", and they failed to follow their policy regarding centrifuge RPM and timer check protocols.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
 Based on document review and interview, the laboratory director failed to ensure a quality assessment program was maintained for one of one assay reviewed (RAST) in 2017 and 2018. Findings Include: 1. Review of quality assessment plan titled, "Northside ENT Quality Assessment Plan," signed by the laboratory director on 9/1/14, read in section "n." of the "Statement of Fact," "...The previous month's quality assurance record should be found and introduced at each monthly QA Review with staff.." 2. Review of the laboratory's monthly quality assessment program for 2017 and 2018 indicated none was available. 3. In interview on 10/1/18 at 2:55 PM, SP-1 confirmed there was no monthly quality assessment documentation to review for 2017 and 2018.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel

have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on document review and interview, the laboratory director failed to ensure one of two moderate complexity testing personnel received the appropriate training for the type and complexity of services offered (RAST testing). Findings Include: 1. Review of CMS-209 [Laboratory Personnel Report (CLIA)], signed by laboratory director on 10/04/18, indicated SP-3 is a moderate complexity testing personnel for RAST testing. 2. Personnel file review indicated no RAST training documentation was available for SP-3. 3. Medical record review indicated the following patient samples were tested by SP-3 for RAST testing (three of eight reviewed): a. PT#2: 6-6-18, RAST=POS/SP-1 and SP-3 b. PT#5: 10-3-17, RAST=POS/SP-3 c. PT#6: 9-12-17, RAST=Neg (Neg=Negative)/SP-3 4. In interview on 10/01/18 at 12:00 PM, SP-1 confirmed the laboratory director failed to ensure SP-3 received the appropriate training for RAST testing.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on document review and interview, the laboratory failed to specify in writing the responsibilities and duties for three of four positions (director, clinical consultant, and technical consultant). Findings include: 1) Review of CMS-209 [Laboratory Personnel Report (CLIA)] signed by the laboratory director on October 4, 2018, indicates SP-2 is the director, clinical consultant, and technical consultant. 2) Review of personnel files indicated the responsibilities and duties for director, clinical consultant, and technical coordinator were not specified in writing and signed by the laboratory director. 3) In interview on 10/01/18 at 12:58 PM, SP-1 stated there were no signed responsibilities approved and signed by the director, for director, clinical consultant, and technical consultant.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory technical consultant failed to evaluate and document annual (2017) competency for two of two testing personnel (SP-1 and SP-3). Findings Include: 1. Review of CMS-209 [Laboratory Personnel Report (CLIA)], signed by laboratory director on 10/04/18, indicated SP-1 and SP-3 are moderate complexity testing personnel. 2. Personnel file review indicated the following hire dates for SP-1 and SP-3: a. SP-1=4/23/12 b. SP-3=8/4/14 3. Review of annual competency evaluations for SP-1 and SP-3 for 2017 indicated none was available. 4. Medical record review indicated the following patient samples were tested by SP-1 and SP-3 for RAST testing (112 tests annually): a. PT#1: 7-6-18, RAST=POS (POS=Positive)/SP-1 b. PT#2: 6-6-18, RAST=POS/SP-1 and SP-3 c. PT#3: 5-3-18, RAST=POS/SP-1 d. PT#4: 4-4-18, RAST=POS/SP-1 e. PT#5: 10-3-17, RAST=POS/SP-3 f. PT#6: 9-12-17, RAST=Neg (Neg=Negative)/SP-3 g. PT#7: 12-6-17, RAST=POS/SP-1 h. PT#8: 11-14-17, RAST=POS/SP-1 5. In interview on 10/01/18 at 12:01 PM, SP-1 confirmed the technical consultant failed to evaluate and perform annual competency for SP-1 and SP-3 in 2017 for RAST testing.