

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1107278	(X3) Date Survey Completed 09/13/2023
Name of Provider or Supplier Growing Kids Pediatrics, Llc	Street Address, City, State 3321 Ballard Lane, New Albany, 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
D0000	A recertification survey was completed on 9/13/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.1250 Analytic Systems 42 CFR 493.1409 Technical Consultant - Moderate Complexity
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the analytic system and correct problems of quality control in the subspecialty Hematology. The laboratory failed to label controls with open date or updated expiration dates (Refer to D5415). The laboratory failed to ensure three of three control levels did not exceed the expiration dates (Refer to D5417). Finally, the laboratory failed to monitor quality control problems in their quality assessment for the analytic system (Refer to D5791).</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to label controls with open date or updated expiration date for three (EightCheck- 3WP Hematology controls: X-TRA-L, X-TRA-N, X-TRA-H) of three controls used on analyzer Sysmex XP-300 (SN: B0623) from 9/07/2023 to the date of the survey and one (PT#7) of nine patients reviewed. Finding include(s): 1. On 9/13/23 at 4:33pm, during the laboratory tour, a Sysmex XP 300 (SN: B0623) was being used for hematology testing. A plastic container labeled "McKesson" with no dates contained 3 level controls (EightCheck- 3WP Hematology controls: X-TRA-L, X-TRA-N, X-TRA-H) bottles inside. The individual bottles of controls did not have an open date or updated expiration date written on the bottle. 2. On 9/13/23 at 4:33 pm, Sp-3 (Testing Person) stated they do not put a date when they open the controls. Sp-3 confirmed all three controls were opened and in use. 3. Review of Sysmex product information for the EightCheck- 3 WP controls, revision date 7/2020, under "Storage and shelf life after first opening" read, "Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 degrees Celsius." 4. Review of Quality Control Instrument printout revealed the three levels of controls without an open date was used on the analyzer Sysmex XP-300 (SN: B0623) prior to running patient PT#7's samples on 9/07/2023. Patient PT Sample Lot ID #/ (PT) Date(s) Control level w/ no date PT#7 9/07/2023 31640710/ Level 1 31640711/ Level 2 31640712/ Level 3 5. Annual Test volume for Hematology is approximately 3,618.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and record review, the laboratory failed to ensure three of three control levels (EightCheck- 3WP Hematology controls: X-TRA-L, X-TRA-N, X-TRA-H) used on analyzer Sysmex XP-300 (SN: B0623) during 2/10/22 through 9/07/23 did not exceed the expiration date for six (PT#1,PT#4,PT#5, PT#6, and PT#7) out of nine patients reviewed. Finding include(s): 1. Review of Quality Control Instrument printout for PT#1, PT#4, PT#5, PT#6, and PT#7 revealed three levels of expired controls were used on analyzer Sysmex XP-300(SN: B0623) prior to running patient samples from 2/10/2022 through 9/07/2023. 2. Patient PT Sample Expiration LOT ID #/ (PT) Date(s) Date(s) Control level PT#1 2/10/2022 2/09/2022 13060710/ level 1 13060711/ level 2 13060712/ level 3 PT#4 10/24/2022 10/19/2022 21930710/ level 1 21930711/ level 2 21930712/ level 3 PT#5 12/16/2022 10/19/2022 21930710/ level 1 21930711/ level 2 21930712/ level 3 PT#6 7/10/2023 6/28/2023 30800710/ level 1 30800711/ level 2 30800712/ level 3 PT#7 4/12/2023 1/11/2023 22770710/ level 1 22770711/ level 2 22770712/ level 3 3. Review of Sysmex product information for the EightCheck- 3 WP controls, revision date 7/2020, under "Storage and shelf life of unopened product" read, when stored at 2-8 degrees Celsius controls "are guaranteed stable until the expiration date stated on the package and vials." Under "Storage and shelf life of unopened product" reads, "Open vials and vials

which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 degrees Celsius." 4. Annual Test volume for Hematology is approximately 3,618.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to monitor quality control expiration dates and failed to record open and expiration dates on quality control materials for three (EightCheck- 3WP Hematology controls: X-TRA-L, X-TRA-N, X-TRA-H) of three controls used on analyzer Sysmex XP-300 (SN: B0623). Finding include(s): 1. The laboratory failed to document open and expiration dates for EightCheck- 3WP Hematology controls: X-TRA-L, X-TRA-N, X-TRA-H controls. Refer to D5415. 2. The laboratory failed to ensure three control levels (EightCheck- 3WP Hematology controls: X-TRA-L, X-TRA-N, X-TRA-H) did not exceed the expiration date. Refer to D5417 3. Review of "Quality Control Statement of facts" not signed by the laboratory director indicated the following guideline(s): I. General laboratory issues, number 7. General Lab system 95% of the time, we have total precision on overall control. 100% of the time, we do not report any patient results unless the controls work 100% of the time, the laboratory staff will review and take corrective actions with QA findings III. Analytic Systems 100% of the time, Quality Control issues are assessed and reconciled, if necessary, using all relevant criteria listed in the regulations. 4. Review of "Quality Assessment Minutes" signed by the laboratory director (SP-1) and testing personnel (SP-2, SP-3, SP-7, SP-8) on 8/30/23. Under QA assessment, II. New QA Problems, "none" was identified, and director assessment was overall "good" for quality control. Expired controls, open dates of control and changes in expiration dates due to dates opened were not mentioned. 5. Annual Test volume for Hematology is approximately 3,618.

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 record review and interview, the laboratory failed to ensure six (SP-3, SP-4, SP-7, SP-9, SP-10, SP-11, and SP-12) of twelve testing personnel were properly trained on the requirements for 1) proper instrument use and 2) verification of patient test results with the evaluation of quality control samples. Findings include(s): 1. On 9

/13/23 at 3:25 pm, during an interview with SP-7 (Testing personnel), when asked for Sysmex XP-300 competency, job descriptions, and initial training documentation for testing personnels (SP-4, SP-10, SP-11, and SP-12). SP-7 stated there was no training documentations on file for these persons. 2. Review of Quality Control Instrument printouts for PT#1, PT#2, PT#3, PT#4, PT#5, PT#6, and SP#7 identified SP-3, SP-7, SP-9, SP-10, SP-11 as the operators (Operator ID) on analyzer Sysmex XP-300(SN: B0623) when expired controls were used and/or no documented training performed prior to instrument use. Testing personnels running expired controls: (Refer to D5417) 1) SP-3 ran expired controls on 2/10/2023 for PT#1 2) SP-7 ran expired controls on 7 /10/2023 for PT#6 Testing personnels running expired controls with no prior training documentation: (Refer to D5417) 3) SP-9 ran expired controls on 12/16/2022 for PT#5 with no training documented on analyzer 4) SP-11 ran expired controls on 10/24 /2022 and 4/12/2023 for PT#4 and PT#7 with no documented training on analyzer. Testing personnel running patient samples with no prior training documentation: 5) SP-10 ran patient samples on 5/24/2022 and 7/27/2022 for PT#2 and PT#3 with no prior training documented on analyzer. 3. Review of "Laboratory Director Responsibilities" document not signed by the laboratory director, under establishment of quality control and quality assurance programs ...number 6 states, "prior to testing patient specimens, ensure that all personnel have appropriate education and training ... and demonstrate reliable testing ability for accurate test reporting". 4. Annual Test volume for Hematology is approximately 3,618.

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 record review and interview, the laboratory director failed specify, in writing the responsibilities of competency assessment to one (SP-2) of two persons qualified to perform the duties of a technical consultant from July 12, 2022, to the date of the survey. Finding include(s): 1. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 9/08/2023, indicated SP-2 is a testing person and was not marked as a technical consultant. 2. Review of personnel files indicated SP-2 had a date of hire of 7/17/2019 and a Bachelor of Nursing degree, but their job description is only for a testing person. They were not assigned duties as a technical consultant and job duties do not include competency assessment. 3. Upon request for competency documentation for SP-3 and SP-5 copies of "XP-300 Training Checklist" was provided. XP-300 Checklist were performed as follows: a) SP-3's check lists were performed on 7/12/2022 and on 7/12/2023 by SP-2. b) SP-5's check lists were performed on 8/15/2023 by SP-2. 4. Review of "Laboratory Director Responsibilities" document not signed by the laboratory director, under establishment of quality control and quality assurance programs indicated the following guideline(s):

7) Establish policies and procedures for monitoring individuals who conduct all phases of testing to ensure competency, reporting, and remedial training to improve skills. 8) Provide to all personnel responsible for the testing process an approved procedure manual. 9) Specify in writing, the responsibilities and duties of each person engaged in the performance of preanalytical, analytical and postanalytical phases of testing. 5. On 9/13/23 at 11:45am, SP-2 confirmed they performed competency for other testing personnel during the periods of July 12, 2022, through the date of the survey. 6. Annual Test volume for Hematology is approximately 3,618.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on document review, the laboratory failed ensure one (SP-5) of three personnel performing responsibilities of a Technical Consultant (TC) was qualified to perform competency from April 12, 2023, to the date of the survey on 9/13/23 (refer to D6035).

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in

biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed ensure one (SP-5) of three personnel performing responsibilities of a Technical Consultant (TC) was qualified to perform competency from April 12, 2023, to the date of the survey on 9/13/23 for analyzer Sysmex -XP300 (SN: B0623). Findings Include: 1. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 9/08/2023, indicated SP-5 is a testing person. 2. Upon request for competency documentation for SP-7, and SP-8 copies of "XP-300 Training Checklist" was provided. XP-300 Checklist were performed as follows: a) SP-7's checklist was performed on 4/12/2023 by SP-5. b) SP-8's checklist was performed on 5/24/2023 by SP-5. 3. Review of personnel files indicated SP-5 had a hire date of 10/12/20 and had a high school diploma. 4. On 9/13/23 at 11:45am, when asked if there were any other documents for competency, SP-2 (Testing person), said "no". Furthermore, SP-2 confirmed SP-5 performed competency for other testing personnel during the periods of 4/12/23 through 8/15/23. 5. Review of "Quality Assessment" document not signed by the laboratory director, under I. General Laboratory Issues, number 5. states "100% of the time, all employees are competent, as verified by the laboratory director". 6. Annual Test volume for Hematology is approximately 3,618.