

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0877934	(X3) Date Survey Completed 05/12/2022
Name of Provider or Supplier Childrens Clinic Of Lufkin Pa, The	Street Address, City, State 205 Gene Samford Ave, Lufkin, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the manufacturer's control package insert, QC records from 1/5/21 to 1/5/22, CMS 116, and confirmed in an interview found the laboratory failed to follow the manufacturer's instruction to verify the new lot number of QC prior to use for Horiba Micro 60 hematology instrument. The findings were: 1. Review of Horiba Medical Hematology Device Minotrol 16 manufacturer's control package insert (15421-004 Rev. 07/15) under 9. Performance and characteristics revealed "Assay values on a new lot of control should be confirmed before it is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the</p>

previous lot are acceptable." 2. Review the laboratory's QC records from 1/5/21 to 1/5/22 revealed the laboratory failed to confirm 9 QC lot numbers prior to put in use for Horiba Micro 60 hematology instrument (SN#: 909CS9897). Lot: MX427 Exp: 2021-03-05 Lot: MX428 Exp: 2021-05-05 Lot: MX429 Exp: 2021-07-05 Lot: MX430 Exp: 2021-09-05 Lot: MX431 Exp: 2021-11-05 Lot: MX432 Exp: 2022-01-05 Lot: MX433 Exp: 2022-03-05 Lot: MX434 Exp: 2022-05-05 Lot: MX435 Exp: 2022-07-05 3. Review the laboratory's CMS 116 signed by the LD on 5/5/22 revealed the annual hematology volume was 1940. 4. An interview with CEO on 5/12/22 at 1:00 pm in the breakroom confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Service LD=Laboratory Director CEO=Chief executive officer

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:
Based on review of the listing of laboratory personnel, annual competency assessment records for 2021, and confirmed in an interview found the technical consultant failed to include direct observation of test performance for 7 of 7 TP for 2 of 2 tests: Horiba Micro 60 hematology instrument and Uricult microbiology test. Findings included: 1. Review of the listing of laboratory personnel revealed 7 TP required annual competency for hematology and microbiology tests. 2. Review of the annual competency assessment records for 2021 revealed the 2021 competency assessment failed to include direct observation of test performance for 7 of 7 TP for Horiba Micro 60 hematology instrument (SN#: 909CS9897) and Uricult microbiology test. TP#1 Hire Date: 10/17/2016 TP#2 Hire Date: 3/11/2020 TP#3 Hire Date: 4/22/2020 TP#6 Hire Date: 10/27/2008 TP#7 Hire Date: 9/30/2019 TP#8 Hire Date: 1/20/2020 TP#9 Hire Date: 8/13/2018 3. An interview with CEO on 5/12/22 at 9:45 am in the breakroom confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Service TP=Testing personnel LD=Laboratory Director CEO=Chief executive officer

D6048

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:
Based on review of the listing of laboratory personnel, annual competency assessment records for 2021, and confirmed in an interview found the technical consultant failed to include monitoring recording and reporting of test results for 7 of 7 TP for 2 of 2 tests: Horiba Micro 60 hematology instrument and Uricult microbiology test. Findings included: 1. Review of the listing of laboratory personnel revealed 7 TP required annual competency for hematology and microbiology tests. 2. Review of the annual competency assessment records for 2021 revealed the 2021 competency assessment failed to include monitoring recording and reporting of test results for 7 of 7 TP for Horiba Micro 60 hematology instrument (SN#: 909CS9897) and Uricult microbiology

test. TP#1 Hire Date: 10/17/2016 TP#2 Hire Date: 3/11/2020 TP#3 Hire Date: 4/22/2020 TP#6 Hire Date: 10/27/2008 TP#7 Hire Date: 9/30/2019 TP#8 Hire Date: 1/20/2020 TP#9 Hire Date: 8/13/2018 3. An interview with CEO on 5/12/22 at 9:45 am in the breakroom confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Service TP=Testing personnel LD=Laboratory Director CEO=Chief executive officer

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the listing of laboratory personnel, annual competency assessment records for 2021, and confirmed in an interview found the technical consultant failed to include reviewing of preliminary results, worksheet, QC, PT, and preventive maintenance for 7 of 7 TP for 2 of 2 tests: Horiba Micro 60 hematology instrument and Uricult microbiology test. Findings included: 1. Review of the listing of laboratory personnel revealed 7 TP required annual competency for hematology and microbiology tests. 2. Review of the annual competency assessment records for 2021 revealed the 2021 competency assessment failed to include reviewing of preliminary results, worksheet, QC, PT, and preventive maintenance for 7 of 7 TP for Horiba Micro 60 hematology instrument (SN#: 909CS9897) and Uricult microbiology test. TP#1 Hire Date: 10/17/2016 TP#2 Hire Date: 3/11/2020 TP#3 Hire Date: 4/22/2020 TP#6 Hire Date: 10/27/2008 TP#7 Hire Date: 9/30/2019 TP#8 Hire Date: 1/20/2020 TP#9 Hire Date: 8/13/2018 3. An interview with CEO on 5/12/22 at 9:45 am in the breakroom confirmed the above findings Key: CMS=Center for Medicare and Medicaid Service PT=Proficiency Test PM=Preventive Maintenance TP=Testing personnel LD=Laboratory Director CEO=Chief executive officer

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:

Based on review of the listing of laboratory personnel, annual competency assessment records for 2021, and confirmed in an interview found the technical consultant failed to include direct observation of instrument maintenance and function checks for 7 of 7 TP for 2 of 2 tests: Horiba Micro 60 hematology instrument and Uricult microbiology test. Findings included: 1. Review of the listing of laboratory personnel revealed 7 TP required annual competency for hematology and microbiology tests. 2. Review of the annual competency assessment records for 2021 revealed the 2021 competency assessment failed to include direct observation of instrument maintenance and function checks for 7 of 7 TP for Horiba Micro 60 hematology instrument (SN#: 909CS9897). TP#1 Hire Date: 10/17/2016 TP#2 Hire Date: 3/11/2020 TP#3 Hire Date: 4/22/2020 TP#6 Hire Date: 10/27/2008 TP#7 Hire Date: 9/30/2019 TP#8 Hire

Date: 1/20/2020 TP#9 Hire Date: 8/13/2018 3. An interview with CEO on 5/12/22 at 9:45 am in the breakroom confirmed the above findings Key: CMS=Center for Medicare and Medicaid Service TP=Testing personnel LD=Laboratory Director CEO=Chief executive officer

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of the listing of laboratory personnel, annual competency assessment records for 2021, and confirmed in an interview found the technical consultant failed to include assessment of problem solving skills for 7 of 7 TP for 2 of 2 tests: Horiba Micro 60 hematology instrument and Uricult microbiology test. Findings included: 1. Review of the listing of laboratory personnel revealed 7 TP required annual competency for hematology and microbiology tests. 2. Review of the annual competency assessment records for 2021 revealed the 2021 competency assessment failed to include assessment of problem solving skills for 7 of 7 TP for Horiba Micro 60 hematology instrument (SN#: 909CS9897) and Uricult microbiology test. TP#1 Hire Date: 10/17/2016 TP#2 Hire Date: 3/11/2020 TP#3 Hire Date: 4/22/2020 TP#6 Hire Date: 10/27/2008 TP#7 Hire Date: 9/30/2019 TP#8 Hire Date: 1/20/2020 TP#9 Hire Date: 8/13/2018 3. An interview with CEO on 5/12/22 at 9:45 am in the breakroom confirmed the above findings Key: CMS=Center for Medicare and Medicaid Service TP=Testing personnel LD=Laboratory Director CEO=Chief executive officer