|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Proficiency Testing** | | | | | | | | |
| **Purpose** | | This process describes Children’s Minnesota’s proficiency-testing (PT) program, including selection or development of proficiency testing, performance and monitoring, review responsibilities and corrective action. | | | | | | |
| **Policy Statements** | | * Inter and intra- lab communication/comparison of results prior to the survey submission deadline is strictly prohibited. * Referral of proficiency samples to another lab with a different CLIA number for analysis is prohibited, even if patient samples would receive further testing to confirm results, such as Lyme’s testing or abnormal blood smears. * Proficiency samples must never be accepted from another laboratory prior to the survey submission deadline. * The laboratory’s CAP Activity Menu must accurately reflect the current testing performed. * Proficiency samples are integrated into routine workload and analyzed by the same personnel who routinely test patient samples. * Repeat analysis of proficiency samples is allowed only to the extent patient samples would be retested for the same test. * Proficiency results must be submitted to CAP or CAP approved facility and the deadline for submission must have passed prior to using PT material as a tool to assess departmental competency. * Follow universal precautions. Refer to the laboratory safety procedures for general safety requirements. Refer to specific procedures for special safety precautions. * Primary PT records are kept for two years, including instrument tapes, worksheets, computer printouts, evaluation reports, evidence of review, and corrective action follow up. | | | | | | |
| **Process** | |  | | | | | | |
|  | | **Step** | **Activity** | | | | **Related Document** | |
|  | | 1 | **Technical Specialists, Supervisors, Designees:**   1. Identify the tests subject to PT. 2. Identify the proficiency testing process:  * Enroll in CAP-approved proficiency testing program. * Participate at least semiannually in alternative performance assessments for those tests for which there are no commercial proficiency testing materials available. * Define limits of acceptability for Alternate PT  1. Develop section-specific proficiency testing process/procedure. | | | | CAP Activity Menu  PT schedule  Department specific PT procedure | |
|  | | 2 | **Medical Directors** and Technical Director review, suggest changes as necessary, and approve PT program. | | | | Approved proficiency testing SOPs and schedule | |
|  | | 3 | **Technical Specialists, Supervisors, Designees** identify personnel rotation schedule. | | | | Proficiency testing schedule | |
|  | | 4 | **Laboratory Staff**   1. Perform PT testing and record results 2. Sign Attestation Statement 3. Incidental or intentional comparison of results with the other system site is strictly prohibited to comply with CAP regulations. | | | | Proficiency test forms | |
|  | | 5 | **Laboratory Leadership, or Designee:**   1. Review PT test results. 2. Complete required PT documentation. 3. Incidental comparison of results by system Technical Specialists or Lead Techs is strictly prohibited according to laboratory and CAP policy. 4. Sign Attestation Statement which attests results have not been shared or communicated with another lab. 5. Submit results to PT agency. | | | | Proficiency test records  Copies of PT reporting forms | |
|  | | 6 | **Laboratory Leadership** reviews the PT testing results. | | | | Proficiency test records | |
|  | | 7 | **Technical Specialists, Supervisors, Designees:**   1. Review/compare reported results with intended results, including ungraded tests. 2. Initiate corrective action for all PT and Alternate PT assessment scores <100%. 3. Document all investigations and corrective action. 4. Retain all proficiency testing records for a minimum of two years. | | | | Proficiency test records  [PT Exception Investigation Worksheet](https://documents-cloud.cap.org/capprd-ccs-acc-resources/PT_Exception_Investigation_Worksheet_2022.pdf?Policy=eyJTdGF0ZW1lbnQiOiBbeyJSZXNvdXJjZSI6Imh0dHBzOi8vZG9jdW1lbnRzLWNsb3VkLmNhcC5vcmcvY2FwcHJkLWNjcy1hY2MtcmVzb3VyY2VzL1BUX0V4Y2VwdGlvbl9JbnZlc3RpZ2F0aW9uX1dvcmtzaGVldF8yMDIyLnBkZiIsIkNvbmRpdGlvbiI6eyJEYXRlTGVzc1RoYW4iOnsiQVdTOkVwb2NoVGltZSI6MTY2NTE2NDAzM30sIkRhdGVHcmVhdGVyVGhhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNjY0NDc3NjMzfX19XX0_&Signature=OkqW5qzwp7PcLpnOzvSBmdFibwe4IKRzpi0GwGwYb2wB0fSS5Ni3RJBkMvuJr6MGRG8iM0PtKcKrll62yi4pnsIVrhwThKARR5zSGLSPJkvxQoc~QU9MToPpJ~ky3ioTzZgfYKFP5EKFu4m38WFU6cgBlHhKVjTKWeUyW-67llTtibvbfVIpP9UhBQjJUR29vXY7AjALI6X4i05ktNjkfAEkDH6eAY4yYkDNGuCyCNhcZLfhuahmkMHvZdacGEixOT3WEv0NiYyia-wnZFuXDHv-WIL-OyTc0OdOhxg1-cz5Etk9W~UUtBMNiIwjpmNLeyQu0uL0a35-D9SsAd1FwQ__&Key-Pair-Id=APKAJQVUA5R3F6PCARGQ) | |
|  | | 8 | **Medical Directors** and Technical Director review and approve all resolutions and corrective action. | | | |  | |
|  | | 9 | **Technical Specialists, Supervisors, or Designees** communicate results to staff. | | | |  | |
| References | | CLSI. The Key to QualityTM. CLSI product K2Q. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.  Berte L., et al, A Model Quality System for the Transfusion Service. Bethesda, MD: American Association of Blood Banks, 1997.  Laessig RH, et al, The New Poor Man’s (Person’s) Guide to the Regulations (CLIA ’88, JCAHO, CAP & COLA). R & S Consultants, July 2002.  Nevalainen D, Berte L., Quality Systems for the Laboratory. Chicago, IL: American Society for Clinical Pathology, 2000.  CLSI. A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.  CAP. *Laboratory Accreditation Program Accreditation Checklists*. Northfield, IL: College of American Pathologists; published annually. | | | | | | |
| **Historical Record** | | **Version** | | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** | |
|  | | | L. Rachford | 07/29/03 | Replaces elements previously in section-specific quality documents | |
|  | | | M. Schumann | 08/10/05 | Revised | |
|  | | | L. Lichty | 06/29/09 | Updated and reformatted, moved policy statements to QP 5.00 | |
|  | | | B. Kochevar | 09/29/09 | Updated and clarified | |
|  | | | L. Lichty | 02/23/2010 | Removed attachments | |
| PMRC/L. Lichty | 7/22/2011 | CMS format | |
|  | | | L. Lichty/PMRC | 10/24/2012 | Policy statements, and steps 4, 5, and 7 | |
|  | | | PMRC/L Lichty | 9/25/2013 | Update header, titles, reference, hyperlink | |
|  | |  | | | Linda Lichty/PMRC | 12/01/2014 | Revised PT sharing statements | |
|  | |  | | | Erin Bartos | 5/21/2019 | Biennial review. Corrected link to exception response form and date for CAP inspection checklist, removed Lead MLS per Lisa K. | |
|  | |  | | | Erin Bartos | 7/8/2020 | Updated titles and links. Updated references. Removed historical record since it is documented in SharePoint. New Medical Director review. | |
|  | |  | | | Matt Johnson | 9/30/2022 | Added Historical Record. Changed exception response form to CAP PT toolbox version. | |