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| **Proficiency Testing Procedures** |
| **Purpose** | This procedure provides instructions for PROFICIENCY TESTING PROCEDURES. The procedures provided describe the process and intent of receiving, distributing, testing, reporting and evaluating results of proficiency testing samples.The purpose of proficiency testing of unknown samples is to promote optimal patient care by demonstrating optimal performance on all analytes for which the laboratory performs patient testing. Proficiency samples are to be integrated as much as possible into the routine daily workload, and handled as patient specimens. All CAP accredited laboratories must be enrolled in CAP or CAP-approved proficiency programs. Subscribers receive unknown specimens on a regular schedule. Results are submitted, evaluated, and compared with peer groups or reference methods performing the same testing. |
| **Policy Statements** | * This procedure is intended for all chemistry personnel
* The lab must not engage in any inter-lab communication pertaining to the results of survey samples until after the survey due date.
* Proficiency samples are never referred to an outside lab, even if patient samples would receive further testing to confirm results, such as Lyme Testing.
* Proficiency samples must never be accepted from another lab prior to the survey due date.
* Proficiency testing samples must be analyzed with the routine workflow of patient samples.
* The laboratory’s CAP Activity Menu must accurately reflect the current testing performed.
* Primary PT records are kept for two years, including instrument tapes, worksheets, computer printouts, evaluation reports, evidence of review, and corrective action follow up.
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| **Materials**  | **Records/Forms/Documents Required*** Survey kit instructions to complete the proficiency activity are included in the mailing.
* Chemistry Proficiency Testing Survey Checklist and internal instructions.
* The PT Exception Investigation Worksheet, on the CAP website, is available as an option to assist in troubleshooting failed PT.
* A PT Compliance Notice (PTCN) form is mailed to the laboratory by the College of American Pathologists to document and inform the CAP of proficiency exceptions corrective action, if required.
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| **Sample** | The specimens are shipped by the proficiency program and may be aqueous, liquid or lyophilized. Instructions are included indicating the number of specimens, specimen handling and stability, testing methods, and safety. |
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|  | **Step** | Action | **Related Document** |
| **Receiving Proficiency Testing Kits** | 1 | The survey kits are received in the lab and promptly given to a Chemistry Department technical staff member. |  |
| 2 | Record the date received and tech initials on the mailing sheet. |  |
|  | 3 | Open the kit and evaluate the samples for leakage, sample contents, correct vial numbers or other observations. Record observations on a Chemistry Proficiency Testing Survey Checklist. | [Chemistry Proficiency Testing Survey Checklist](http://khan.childrensmn.org/Manuals/Lab/SOP/Chem/Forms/204031.pdf) |
|  | 4 | Store the survey kit as indicated by the kit instructions. |  |
|  | 5 | Notify the Technical Specialist when survey samples arrive and if additional samples are needed.  |  |

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|  | **Step** | Action | **Related Document** |
| **Proficiency Sample Assignment** | 1 | The Technical Specialist or designee will assign proficiency samples. Proficiency samples will be assigned evenly according to staffing availability during the time of testing. |  |
|  | 2 | Review all test methods and reagent codes for accuracy. |  |
|  | 3 | Indicate testing to be performed on each sample on the PT Survey Checklist as appropriate. |  |
|  | 4 | As appropriate, alert testing personnel of unit conversions if required for reporting. |  |
|  | 5 | Survey sample assignments will be communicated by email or in person. |  |
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|  | **Step** | Action | **Related Document** |
| **Processing Proficiency Samples** | 1 | Read completely and follow carefully the instructions provided with the survey kit before removing samples from storage. Remove only the sample(s) assigned from storage if not performing the whole survey. |  |
|  | 2 | Testing should be performed in a timely manner to meet specimen stability requirements. Testing must be completed 7 days in advance of the survey due date whenever possible to allow for the review and submission of results to CAP. |  |
|  | 3 | Perform the required testing on the survey specimens in the same manner as patient specimens; performing QC, repeat protocols, and dilutions. Follow the method procedure unless the survey instructions indicate otherwise. Do not run the sample in duplicate unless you are expressly directed to do so by the survey instructions or Technical Specialist, or if routine patient testing (i.e. osmolality).  |  |
|  | 5 | Blank CAP survey report forms no longer come with survey kits. If desired, these may be printed from the CAP website. Print, then transcribe results to the CAP survey report form copy from the original analyzer printout, or manual result form as applicable. Double check transcription and reporting units. This step is optional. |  |
|  | 6 | Indicate on the result form any testing discrepancies, such as sample stability time exceeded, inability to perform testing, etc. |  |
|  | 7 | Sign PT Attestation Statement for CAP or WSLH and complete the Chemistry PT Survey Checklist. |  |
|  | 8 | Return survey samples to recommended storage. |  |
|  | 9 | Once all survey testing is completed, place the vials into a biohazard bag in the Chemistry survey freezer. Use one biohazard bag per survey. Whole blood samples are stored in the Chemistry refrigerator, as are samples for blood gas or co-oximetry analysis and chemistries on body fluids. Turn paperwork in to Technical Specialist or designee.  |  |
| **Result Reporting** | 1. TS, Lead, or Designee will review test results, reporting units, methods, and instrument codes for accuracy and completeness.
2. Enter data into CAP website and submit:
	1. Enter data per printouts, photocopied worksheets, or as transcribed by performing tech(s).
	2. The attestation page will include the Director or designee, and performing tech(s).
3. Print and review:
	1. Print a copy of results as they were submitted as well as the transaction history to show receipt by CAP.
	2. Review the printed copy each test for correct method, units. Review each result for typos, transpositions, calculations. Use checkmarks to indicate each piece of data was reviewed.
	3. Review and mark each blank test or omitted result to confirm submission is not required. If a method code is listed and no result is entered, either ensure exception code is entered or test is performed and submitted as applicable.
	4. Initial and date each page as reviewed.
	5. If corrections are needed, enter, submit, and print corrected data. Review per above process.
	6. The printed results must stay at the testing location and may not be shared with other locations until after submission deadline.
	7. Sign PT Survey Checklist once complete. (Submitted by line)
4. Submission review:
	1. Second review of submitted results should be completed prior to the submission deadline, either by a second person or by the submitter on a different day.
	2. The printed copy of submitted results will be compared to the original copy of results from the instrument or manual resulting worksheet.
	3. Review the printed copy each test for correct method, units. Review each result for typos, transpositions, calculations. Use checkmarks to indicate each piece of data was reviewed.
	4. Review and mark each blank test or omitted result to confirm submission is not required. If a method code is listed and no result is entered, either ensure exception code is entered or test is performed and submitted as applicable.
	5. Initial and date each page as reviewed.
	6. If corrections are needed, enter, submit, and print corrected data. Review per above process.
	7. The printed results must stay at the testing location and may not be shared with other locations until after submission deadline.
	8. Sign PT Survey Checklist once complete. (Reviewed by line)
5. Shared surveys between chemistry and hematology require communication with the hematology Technical Specialist throughout the PT submission process to ensure both departments have results submitted on time.
6. Test performance and data submitted are evaluated and recorded in the proficiency testing grid available on the shared drive.
7. Results must be received by the Proficiency provider no later than the stated due date.
8. If faxing results, obtain a confirmation report and retain with the completed survey.
9. File all forms and results in the designated 3-ring binder.
10. The lab must not engage in any inter-lab communication pertaining to the results of survey samples until after the survey due date.
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| **Interpretation/ Results/Critical Values** | 1. Review of the PT Evaluation is documented on the PT Evaluation, and the PT Exception Investigation Worksheet as applicable.
2. Evaluate ungraded and Alternate Performance Assessment results and determine acceptability of responses. If PT provider does not provide guidelines, acceptable results should be the peer mean ± 2 SD, 2.5 SDI or CLIA guidelines when available. Refer to the section in the CAP Participant Summary called “Actions Laboratories Should Take when a PT Result is Not Graded”.
3. Review and grade a result in the event results are not graded due to late submission, incorrect units or method code, non-consensus between reporting labs, etc. using the peer mean and SD.
4. Evaluate results over time for shifts or trends to determine method accuracy or inconsistency. The review for bias is indicated by a check-mark next to the bar graph on the Evaluation Report.
5. Unsatisfactory performance must be investigated, and may include:
	1. Review of the original work.
	2. Recheck transcription, calculations, dilutions, and units.
	3. Check QC results, calibration results, and method performance.
	4. Rerun the original sample.
6. Investigations will be recorded and summarized on the PT Exception Investigation Worksheet
7. The Technical Specialist or designee will:
	1. Review all findings
	2. Implement process improvements as needed to prevent future occurrence.
	3. Complete necessary documentation, and review with Medical Director.
8. PT Evaluations, PT Exception Investigation Worksheets, and Participant Summary Reports are filed in the designated 3-ring binder with all the original documents or saved as a PDF to the shared drive.
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| **Limitations** | Survey results must be reported in the correct units, which may be different than the units used at Children’s for reporting patient results. The following conversion factors may be needed for reporting survey results:* Ionized Calcium: mEq/L divided by 2 = mmol/L
* Lactate: mg/dL x 0.111 = mmol/L
* CRP: mg/dL x 10 = mg/L
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| **References** | 1. College of American Pathologists Survey Manual, Sections III, VI, and VIII, 1992
2. College of American Pathologists LAP, Chemistry and Toxicology Checklist, 06/04/2020
3. College of American Pathologists LAP, All Common Checklist, 06/04/2020
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Unknown | 1984 | Initial Version |
|  | CJC | 7/1990 |  |
|  | JKT | 3/1992 |  |
|  | K. Carlson | 8/1997 |  |
|  | L. Lichty | 06/2003 |  |
|  | L. Lichty | July 12, 2007 |  |
|  | D. Helfinstine | 04/01/2011 | New Format, renumbered from CH 0.12 |
|  | L. Lichty | 10/1/2012 | Added IgG subclass limitation |
|  | Linda Lichty | April 29, 2013 | Add evaluation for ungraded results, PT Exception Response Checklist, prohibit referring samples to outside lab. |
|  | Linda Lichty | September 11, 2013 | Revised ammonia acceptability to 3 SD |
|  |  | Linda Lichty | November 3, 2014 | Added 3 policy statements, removed QC data submission, removed unit corrections for CA and MG, added statement #2 to Result Reporting. |
|  |  | Erin Bartos | 6/1/2017 | Change evaluation of PT results from 2 SDI to 2.5 SDI. Added “designee” to certain steps of process. Updated link for exception summary response form. |
|  |  | Erin Bartos | 10/5/2018 | Added two individuals reviewing prior to the due date for clerical errors, testing must be completed 1 week prior to due date whenever possible, samples frozen in one biohazard bag per survey as soon as sample is completed (when applicable), removed T3 conversion factor, survey kits should be given to a chemistry technical staff member |
|  |  | Erin Bartos | March 1 2021 | Communication with TS of hematology required for shared surveys. |
|  |  | Matt Johnson | June 14, 2021 | Process revision, multiple changes. Removed Sunquest ordering. Removed use of PT as competency assessment.  |
|  | Matt Johnson | 5/11/2022 | Moved to Quality section from Training, renumbered from CH 1.03 |
|  | 16 | Matt Johnson | 10/12/2022 | Added additional steps to result reporting section. Minor updates to interpretation section. |