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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*** All necessary forms and documents to complete the proficiency activity are included in the mailing.
* Chemistry Proficiency Survey Checklist and internal instructions.
* The [PT Exception Investigation Checklist](http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=eLAB_page&eLabSol=eLABPT_page), on the CAP website, is available as an option to assist in troubleshooting failed PT.
* An internal [Proficiency Testing Exception Response Form](http://intranet.childrensmn.org/References/labsop/qual/proc/qp-5.50.f1-pt-exception-response-form.pdf) is used for internal documentation of investigation of proficiency exceptions.
* A PTES 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 Survey Checklist. | [Chemistry Proficiency Survey Checklist](http://khan.childrensmn.org/Manuals/Lab/SOP/Chem/Forms/204031.pdf) |
|  | 4 | Store the survey kit as indicated in the kit instructions. |  |
|  | 5 | Notify the Technical Specialist by Sunquest mailbox when survey samples arrive and if additional samples are needed.  |  |

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|  | **Step** | Action | **Related Document** |
| Creating Proficiency Test Orders in Sunquest | 1 | Order the appropriate tests in Sunquest Gateway under the Order Entry folder. |  |
| 2 | Patient ID: Enter CSVS- for STP or CSV- for Mpls. The system will assign the ID number. |  |
|  | 3 | Name: enter CHEM for Mpls or CHEMS for STP, and the survey material vial identification, i.e. CHEM,CHM-01 or CHEMS,AQ-11 |  |
|  | 4 | DOB: enter “T” or a dummy date |  |
|  | 5 | Sex: Enter “M” or “F” |  |
|  | 6 | Click on “New Episode” and “Save” |  |
|  | 7 | Collect Time: Enter “N” for now. |  |
|  | 8 | In the yellow “Order Code” field, enter the test codes of testing to be performed: i.e. BILI, TSH, IGE, etc. |  |
|  | 9 | Click on “Assign Acc”. Record this number on the result sheet. Click “Save” |  |
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|  | **Step** | Action | **Related Document** |
| **Distribution of Proficiency Samples** | 1 | The Technical Specialist or designee will distribute proficiency samples. Proficiency samples will be distributed evenly according to staffing availability during the time of testing. |  |
|  | 2 | Review all test methods and reagent codes for accuracy. |  |
|  | 3 | Highlight testing to be performed on each sample on the Survey Result Form. |  |
|  | 4 | Alert testing personnel of unit conversions if required for reporting. |  |
|  | 5 | Survey sample assignments will be communicated by Sunquest mailbox or Groupwise. |  |
|  | 6 | Proficiency testing performance is a component of Competency Assessment for employees. Each employee is required to report proficiency results from the instrumentation from which they report patient samples, as samples are available.  |  |
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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, including use of Sunquest labeling, 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. |  |
|  | 4 | Enter survey sample results in Sunquest. |  |
|  | 5 | Transcribe results to the CAP survey report form copy from **the original analyzer printout, not the Sunquest report**. Double check transcription and reporting units. |  |
|  | 6 | Indicate on the result form any testing discrepancies, such as sample stability time exceeded, inability to perform testing, etc. |  |
|  | 7 | Complete the Chemistry Proficiency Survey Checklist, and attach a copy of the Sunquest patient report. Include Tech ID or initials. |  |
|  | 8 | Sign the testing Attestation Statement for CAP or WSLH indicating samples were handled in the same manner as a patient sample. |  |
|  | 9 | Return survey samples to recommended storage. |  |
|  | 10 | As each sample is completed, whether by the same or different technical staff, 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. |  |
| **Interpretation/ Results/Critical Values** | 1. Review of the evaluated results is done by the Laboratory Administrative Director, and forwarded to the Technical Specialist. Each reviews, signs, and dates the Evaluation Form.
2. Evaluate ungraded and Alternate Performance Assessment results and determine acceptability of responses. Acceptable results should be the peer mean ± 2 SD, 2.5 SDI or CLIA guidelines when available. Acceptable results for Ammonia should be the peer mean ± 3 SD. 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. The Evaluation and Participant Summary Reports are filed in the designated 3-ring binder with all the original documents.
6. Unsatisfactory performance must be investigated by the responsible tech:
* Review the original work.
* Recheck transcription, calculations, dilutions, and units.
* Check QC results, calibration results, and method performance.
* Rerun the original sample.
* Submit findings to the Technical Specialist within 1 week of request.
1. The Technical Specialist will:
* Review all findings and write up the Exception Response Form.
* Implement process improvements as needed to prevent future occurrence.
* Complete necessary documentation, and review with Medical Director, and Laboratory Director if required.
* Obtain Medical Director or Laboratory Director signature as required.
* Return the Exception Response Form to the CAP if required.
* File all documents with original survey reports.
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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 divided by 9 = mmol/L
* CRP: mg/dL x 10 = mg/L
* IgG Subclasses are reported as the instrument measured value, not the Sunquest calculated results
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| **Result Reporting** | 1. When testing is completed, the Technical Specialist or designees review test results, reporting units, methods, and instrument codes for accuracy.
2. The Technical Specialist or designee assures all testing has been completed on time, all forms are completed accurately and completely, and the Attestation Statement is signed by all testing personnel.
3. Two individuals should review submitted results prior to the due date whenever possible to decrease transcription errors.
4. Test performance and data submitted are evaluated and recorded in the proficiency testing grid available on the G:drive.
5. The Technical Specialist signs the completed Result Forms as “Director or Designee” or obtains the Medical Director’s signature.
6. Results must be received by the Proficiency provider no later than the stated due date.
7. Results for CAP proficiency material can be submitted on-line at [www.cap.org](http://www.cap.org) by authorized staff. Instructions are available on the website. When submitting the survey online, print a copy of the transaction summary to file with the paperwork to document receipt of data.
8. When 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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| **References** | 1. College of American Pathologists Survey Manual, Sections III, VI, and VIII, 1992
2. College of American Pathologists LAP, Chemistry and Toxicology Checklist, 8/21/2018
3. College of American Pathologists LAP, All Common Checklist, 08/21/2018
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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 |