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| Instrument Comparison | | | | | | |
| **Purpose** | This procedure provides instructions for INSTRUMENT COMPARISON. This procedure describes the activity used to meet regulatory requirements for reporting results for the same test from different analyzers. This procedure is intended for all Chemistry personnel responsible for the comparison of test values reported across multiple analyzers in the same lab, and under the same CLIA license. | | | | | |
| **Policy Statements** | * This procedure applies to all employees working in the chemistry department * When more than one non-waived instrument/method is used to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results. * These requirements do not apply to calculated or derived parameters or when the instruments/reagents are not producing the same reportable result. * Comparability criteria are defined by considering known bias between methods, CLIA limits, and clinically significant medical decision points. | | | | | |
| **Materials** | **Reagents, Supplies, Equipment:**  Refer to the specific method procedures for required reagents, equipment and supplies. | | | | | |
| **Special Safety Precautions** | Refer to the manufacturers’ and laboratory’s safety policies and procedures for the analyzers being checked. | | | | | |
| **Procedure** | **Step** | Action | | | | **Related Document** |
|  | 1 | Blood Gas and Hematology analyzers, Twice Yearly: Each blood gas analyzer will be tested twice per year against a like analyzer and the hematology analyzer as follows:  Minneapolis Sample 1: ABL90 MABL1, ABL90 MABL2, and Sysmex XN  Minneapolis Sample 2: ABL90 MABL3, ABL90 MABL4, and Sysmex XN  St. Paul Sample 1: ABL825 SABL1, ABL825 SABL2, and Sysmex XN  The Sysmex/ABL comparison applies only to Hemoglobin testing. The other analytes as shown on the comparability worksheet.   * Choose a patient sample in which an EDTA whole blood sample and a heparinized syringe were drawn within 10 minutes of one another (or draw both samples from a lab employee). * Ensure both are mixed thoroughly as hemoglobin is sensitive to mixing errors. * Run the EDTA whole blood on the Sysmex for hemoglobin, and run the syringe on 2 blood gas analyzers. * In Minneapolis, use two separate patient/employee samples so that all 4 gas analyzers are tested according to the schedule above. Wait until the specified blood gas analyzers are in the lab before proceeding with the comparison study. | | | | [CH 2.05.f1 Blood Gas Instrument Comparison](https://starnet.childrenshc.org/References/labsop/chem/forms/ch-2.05.f1-blood-gas-instrument-comparison.pdf) |
|  | 3 | **Chemistry Instruments and Blood Gas Instruments, Twice Yearly:**  Minneapolis Sample 1: Vista VISM, Alinity c MALIC, MABL1 and MABL4  Minneapolis Sample 2: Vista VISM, Alinity c MALIC, MABL2 and MABL3  St. Paul Sample 1: Vista VISS, Architect ARCH4, SABL1, and SABL2   * Select (or draw from a lab employee) a heparinized plasma sample with enough volume to run on 2 chemistry and 2 blood gas analyzers. * Ensure the sample is spun soon after draw, that there is no time delay between testing on each analyzer, and that evaporation artifacts are minimized. * Follow the schedule listed above. In Minneapolis, wait until the specified blood gas analyzers are in the lab before proceeding with the comparison study. | | | | CH 2.05.f2 Chemistry and Blood Gas [Instrument](https://starnet.childrenshc.org/References/labsop/chem/forms/ch-2.05.f2-chemistry-and-blood-gas-instrument-comparison.pdf) Comparison |
|  | 6 | Run patient samples simultaneously on the analyzers being compared, following method procedures. Ensure whole blood samples are mixed thoroughly, and for all samples, avoid time delays due to analyte stability and evaporation effects. | | | |  |
|  | 7 | Record results on applicable worksheets listed under Related Documents. | | | |  |
|  | 8 | Calculate the actual difference and/or % difference as needed. | | | |  |
|  | 9 | Record whether observed differences meet defined criteria: Y(es) or N(o) | | | |  |
|  | 10 | If acceptable limits are exceeded, identify the problem(s) and correct them before repeating analysis. Record all troubleshooting steps on the worksheet. Troubleshooting steps may include:   1. calibrating if the current calibration is nearing expiration 2. checking the number of tests left in the reagent pack (results become less stable as the reagent deteriorates) 3. reviewing for sample integrity issues such as delays, mixing errors, and bubbles 4. checking for potential instrument malfunctions such as pipette errors or dirty cuvettes | | | |  |
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| **Calculations** | To calculate the % difference, divide the difference between the 2 results by the target or deemed value. | | | | | |
| **Interpretation/ Results/Critical Values** | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Analyte** | **Children’s Acceptability Criteria** | | **Known Method Bias: Abbott to Vista** | **CAP Proficiency Testing Criteria** | | PH | ± 0.04 | | n/a | ± 0.04 | | PCO2 | ± 5.0 mm Hg or 8% | | n/a | ± 5.0 mm Hg or 8% | | PO2 | ± 5 mm Hg or 15% if >100 | | n/a | ± 3 SD | | METHB | ± 2 | | n/a | ± 2 | | COHB | ± 3 | | n/a | ± 3 or 3 SD | | O2HB | ± 3 | | n/a | ± 3 or 3 SD | | HGB | ± 0.6 g/dL or 7% | | n/a | ± 7% | | ICA | ± 0.2 mEq/L | | n/a | ± 3 SD | | NA | ± 4 mEq/L | | - | ± 4 mEq/l | | K | ± 0.5 mEq/L | | 3% | ± 0.5 mEq/L | | CL | ± 5 or 5% | | - | ± 5% | | GLUC | ± 6 mg/dL or 10% | | 3% | ± 6 mg/dL or 10% | | Lactate | ± 4 mg/dL | | n/a | 0.4 mmol/L or 3 SD | | TCO2 | ± 5 mEq/L  (Not applicable to calculated results on ABLs.) | | -10% | ± 3 SD | | BUN | ± 2 mg/dL or 9% | | 2% | ± 2 mg/dL or 9% | | CREA | ± 0.3 mg/dL or 15% | | 3% | ± 0.3 mg/dL or ± 15% | | CALCIUM | ± 1.0 mEq/L | | 9% | ± 1.0 mg/dL | | CRP | ±10% or 0.1 mg/dL | | 10% | ±3 SD | | ALT | ±30% if <100, 20% over 100 | | -10% at lower levels | ±20% | | ALK | ±30% | | -5% | ±30% | | AST | ±25% over 100, 20% less than 100 | | -5% at higher levels | ±20% | | ALB | ±20% | | 11% | ±10% | | TP | ±10% | | -2% | ±10% | | DBI | ±0.4 mg/dL or 20% | | - | ±0.4 mg/dL or 20% | | TBI | ±0.4 mg/dL or 20% | | 7% | ±0.4 mg/dL or 20% | | MG | ±25% | | -4% | ±25% | | PO4 | ±0.5 or 10.7% | | 4% | ±0.3 mg/dL or 10.7% | |  | |  | | | | | | | | |
| **Result Reporting** | Record all results on the appropriate Instrument Comparison log and file in appropriate comparison binder. Results are reviewed periodically by the Technical Specialist or designee. | | | | | |
| **References** | College of American Pathologists, Commission on Laboratory Accreditation, Chemistry All Common Checklist, Revised 09/17/2019 | | | | | |
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| **Historical Record** | **Version** | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** | |
|  | | K. Carlson | 9/1997 | Initial Version | |
|  | | D. Riedel | no date |  | |
|  | | L. Lichty | 9/2003 |  | |
|  | | L. Lichty | 5/2007 |  | |
|  | | L. Lichty | 11/2/2010 | Revised frequency | |
|  | | L. Lichty/D. Helfinstine | 04/01/2011 | New Format, added extra analytes to MPLS correlation, changed HGB correlation frequency, renumbered from CH 0.08 | |
|  | | L. Lichty | 2/26/13 | Adjust pO2 acceptability, fix hyperlinks | |
|  |  | | L. Lichty | 6/1/2015 | Updated for Vista | |
|  |  | | Kelsi Brown | April 21, 2017 | Updated for Sysmex XN | |
|  |  | | Kelsi Brown | April 22, 2019 | Added criteria for ABL90s and removed ABL80. | |
|  |  | | Erin Bartos | May 7, 2019 | Corrections to wording and instructions. | |
|  |  | | Erin Bartos | February 3, 2020 | Updated for Abbott instrumentation, changed timing to match CAP regulatory requirements, changed limits to include known methodology differences between Siemens and Abbott, removed TCO2 from gas/chemistry due to calculated results on ABLs, changed schedule of instruments compared. | |
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