| **Prolactin** |
| --- |
| **Purpose** | This procedure provides instructions for performing PROLACTIN on ABBOTT INSTRUMENTATION. The Alinity i Prolactin Calibrators are for the calibration of the Alinity i analyzer when used for the quantitative determination of prolactin in human serum and plasma.  |
| **Policy Statements** | This procedure applies to all personnel responsible for operating Alinity ci at Children’s Minnesota Laboratory in Minneapolis. |
| **Principle** | This assay is a two-step immunoassay for the quantitative determination of prolactin in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.Sample and anti-prolactin (mouse, monoclonal) coated paramagnetic microparticles are combined and incubated. The prolactin present in the sample binds to the anti-prolactin (mouse, monoclonal) coated microparticles. The mixture is washed. Anti-prolactin (mouse, monoclonal) acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of prolactin in the sample and the RLUs detected by the system optics.For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | Human prolactin (hPRL) is a single chain polypeptide of 199 amino acids and a molecular weight of approximately 23 000 daltons. Its existence as a distinct chemical entity, separate from growth hormone, was established through a series of studies between 1965 and 1971. Prolactin is produced by the anterior pituitary and its secretion is regulated physiologically by inhibitory and releasing factors of the hypothalamus. Prolactin appears in the blood promptly after administration of thyrotropin-releasing hormone (TRH). The major physiologic action of prolactin is the initiation and maintenance of lactation in women.Hyperprolactinemia has been established as a common cause of infertility and gonadal disorders in men and women. Prolactin has been shown to inhibit the secretion of ovarian steroids and to interfere with follicle maturation and the secretion of LH and FSH in the human female. Measurement of elevated serum prolactin levels may provide the first quantitative evidence of pituitary dysfunction. Quantitation of prolactin levels is also of interest in the evaluation and management of patients with amenorrhea and galactorrhea. Various factors other than disease states have been found to influence prolactin levels. Factors which increase prolactin concentrations include: pregnancy, breast stimulation, stress, coitus, administration of estrogens, progesterone, androgens, some psychotropic and antihypertensive drugs, and TRH. Factors which decrease prolactin concentrations include the administration of L-dopa and bromocriptine.The Alinity i Prolactin assay is to be used as an aid in the diagnosis of male and female infertility and pituitary dysfunction, monitoring of male and female gonadal disorders and management of amenorrhea and galactorrhea. |
| **Analyzer** | **Minneapolis: Abbott Alinity i (Sunquest method code: MACI)****Backup:** Hold samples until instrument is back in service. If urgent or directed by provider, send to Mayo Medical Laboratories (PRL) |
| **Sunquest Test Codes** | **PROL** Prolactin |
| **Specimen** | Sample: Serum or Plasma (with or without gel barrier)**Preferred:** SST**Alternative:** Lithium Heparin, Sodium Heparin, EDTA**Minimum sample volume:** 0.75 mL blood, 0.25 mL serum/plasmaMaximum number of replicates sampled from the same sample cup: 10Priority loaded: Sample volume for first test: 80 μL Sample volume for each additional test from same sample cup: 30 μLLoaded routinely: Sample volume for first test: 150 μL Sample volume for each additional test from same sample cup: 30 μL**Stability when separated from cells/gel:** **20 to 25°C** Not specified. Remove to storage at least once every shift.**2 to 8°C** 7 days**-20°C** 12 months**Rejection criteria:** Unlabeled tube, sample type other than serum or acceptable plasma**Preparation:** 1. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
3. Specimens should be free of particulate matter.
4. Transfer serum or plasma directly to a properly labeled pilot tube.
5. Architect and Alinity systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required.
6. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
 |
| **Reagents** | **Reagent Handling** Upon receipt, gently invert the unopened reagent kit by rotating it over and back for a full 180 degrees, 5 times with green label stripe facing up and then 5 times with green label stripe facing down. This ensures that liquid covers all sides of the bottles within the cartridges. During reagent shipment, microparticles can settle on the reagent septum.**Place a check in the square on the reagent kit to indicate to others that the inversions have been completed.**After mixing, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate. Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results. Use a pipette to remove all bubbles prior to loading on the Alinity or Architect system.* Do not use reagents beyond the expiration date.
* Do not pool reagents within a kit or between kits.
* Do not use components from one lot with components from another lot.
 |
|  |

|  |  |  |
| --- | --- | --- |
| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Alinity i Prolactin Reagent Kit  | 07P6620 | **Store at:** 2 to 8°C **Unopened:** Until expiration date. If cartridge does not remain upright, gently invert the cartridge 10 times and place in an upright position for 1 hour before use.**On-board**: 30 days.If removed, Store in upright position. If cartridge does not remain upright during storage, discard the cartridge.Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance. |
| Alinity i Prolactin Calibrator Kit | 07P6601 | **Store at:** -10°C or colder**Unopened:** Until printed expiration date**Opened expiration:** Up to 60 days after thaw, not to exceed the expiration date printed on the bottle. Store tightly capped with new replacement cap. After each use, immediately return the thawed calibrators to refrigerated storage (2 to 8°C).The analyzer will track In-use Stability, which is the time the calibrator is outside of refrigerated storage while on the analyzer.The analyzer will not allow the use of the calibrator if the In-use Stability has been exceeded. Maximum In-use Stability can be found in the Assay Parameter Report. |

 |
| **Risk and Safety** | **CAUTION:** This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents**The following warnings and precautions apply to:** *Conjugate* **WARNING** Contains methylisothiazolones. May cause an allergic skin reaction**The following warnings and precautions apply to:** *Cal 1-Cal 2* **CAUTION:** This product contains human-sourced and/ or potentially infectious components. Refer to the CONTENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that this product and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.Contains sodium azide.Contact with acids liberates very toxic gas.Special reagent disposal not indicated.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

|  |  |
| --- | --- |
| Assay Range: | 0.82 to 200.00 ng/mL |
| Reference Material: | Abbott Alinity i Prolactin Calibrators |
| Suggested Calibration Levels: | CAL 1: 5.00CAL 2: 30.00 |
| Calibration Scheme: | 2 Levels |
| Calibration Frequency: | With every new lot number, after maintenance or service of major instrument parts, as indicated by quality controls, and as directed by field service representatives. |
| AMR | AMR is verified twice annually using the AUDIT K833M-5 by running all applicable levels in triplicate. Assay results are submitted to Audit Microcontrols and/or entered in EP Evaluator for compilation. Results are reviewed and approved by the Technical Specialist. Questionable results are investigated and corrective actions documented. |

 |
| **Quality Control** | **QC Material:** BioRad Liquichek Immunoassay Plus Levels 1,2 and 3 **Frequency:** Three levels each day of use. **Stability:** 5 Days at 2-8°C (due to the inclusion and use of Estradiol in this control) **Preparation**: Let vials thaw for 30 minutes at room temperature and gently swirl to ensure homogeneity. Do not allow to stand at room temperature longer than 20 minutes after completely thawed. **Acceptable ranges:** * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules.
* New lots of Bio-Rad controls should be run for 20 days in parallel with the current lot whenever possible prior to switching to the new lot.
* Refer to the Westgard Rules in Chemistry procedure for current Westgard rules in place for each analyte.
* **Acceptable ranges are current in Unity Real Time only.** Quality Control results must be rejected in Sunquest when the results cross the interface.
* In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section.
* Do not load or release patients until QC is acceptable in Unity Real Time.
 |
| **Interferences** | This study was performed on the ARCHITECT i System. Potential interference from hemoglobin, bilirubin, triglycerides, and protein was studied in the ARCHITECT Prolactin assay. The ARCHITECT Prolactin assay demonstrated less than 10% interference for the following potentially interfering substances:Hemoglobin ≤ 500 mg/dLBilirubin ≤ 20 mg/dLTriglycerides ≤ 3000 mg/dLProtein ≤ 12.0 g/dL |
| **Reference Intervals** | **Male and Female:**<30 Days: 12.6 - 21330 Days to <1 Year: 6.3 - 114 1 to < 19 Years: 4.2 - 23.0**Adult Male:** 3.46 - 19.40 **Adult Female**: 5.18 - 26.53 |
| **Critical Values** | None specified |
| **Limitations** | Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.If the prolactin results are inconsistent with clinical evidence, additional testing is recommended.Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as Alinity i Prolactin that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.Prolactin may exist in alternate structural forms (e.g. macroprolactin) which may exhibit variable levels of physiological activity. In patients with elevated prolactin results, additional information may be required for diagnosis. |
| **Dilutions** |

|  |  |
| --- | --- |
| Max Auto Dilution: | 1:10 |
| Maximum Manual Dilution: | None |
| Diluent: | Onboard diluent |
| Automated Dilution: | Follow Abbott [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated dilutions. The system will automatically calculate the concentration of the sample and report the result. If a diluted sample result is less than the lower value of the measuring interval of 0.82 ng/mL, do not report the result. Rerun and/or investigate for other possible causes of error. |

 |
| **Result Reporting** | * Results between 0.82 and 200.00 ng/mL without error messages are released
* Results below 0.82 without error messages are reported as < 0.82 ng/mL.
* Results > 200.00 should be diluted using the onboard automated 1:10 dilution. Release results without error messages following this dilution.
* Results > 2000.00 following automated dilution are reported as > 2000.00.
 |
| **Specimen Storage** | Promptly stopper tested specimen and store upright in a specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 14 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity i Prolactin Reagent Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018
2. Abbott Alinity i Prolactin Calibrator Kit Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018
3. CALIPER Reference Interval Studies, accessed 10/27/2020.
4. BioRad Liquichek Immunoassay Plus Quality Control Package Insert, BioRad Laboratories, Irvine, CA. Revised April 2020
 |
| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Elauteria Earnhardt | May 18, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Correct instrument and backup, number assigned, added AMR, reagent and calibrator information, added dilution, references, reference intervals, etc for new instrument. |