| **IgE** |
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| **Purpose** | This procedure provides instructions for performing IMMUNOGLOBULIN E (IgE) in Children’s Minnesota Laboratory.The QUANTIA IgE Assay, distributed by Abbott Diagnostics, is an automated latex enhanced immunoassay for the quantitative in vitro determination of Immunoglobulin E (IgE) in human serum or plasma (EDTA, heparin, citrate) using the ARCHITECT c Systems. The measurement of IgE is useful in the clinical diagnosis of IgE-mediated allergies, if used in conjunction with other clinical studies. |
| **Policy Statements** | * This procedure applies to all personnel who perform patient testing on the Abbott Architect c4000.
* All components of individual QUANTIA IgE Assay reagent kits must not be shared between kits.
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| **Principle** | The Quantia IgE reagent is a suspension of polystyrene latex particles of uniform size coated with mouse anti-human IgE. When a sample containing IgE is mixed with the latex reagent and the reaction buffer included in the kit, agglutination occurs. The degree of agglutination is directly proportional to the concentration of IgE in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.**Methodology**: Turbidimetric/Immunoturbidimetric  |
| **Clinical Significance** | The highest IgE values are found in atopic dermatitis. There is a certain correlation between chronic allergen exposure and the level of total IgE. However, verification of diagnosis can only be performed by appropriate in vitro and in vivo diagnostic tests. The measurement of IgE is indicated in diagnosing allergies, extended investigation of allergies, illnesses associated with eosinophilia or fever of unknown origin, congenital immunodeficiency syndromes, and acquired immunodeficiency syndromes.In clinically healthy subjects, serum IgE levels exhibit a wide distribution range and do not follow a normal distribution. Age related concentrations must be taken into account when interpreting IgE values in children. IgE does not cross the placental barrier so IgE is not detectable in neonates. The IgE concentration increases during the first years of life, reaching a peak at 10 to 15 years and dropping subsequently to adult values. |
| **Analyzer** | **Abbott Architect c4000**, St. Paul: SN c461801**Backup method**: Mayo Medical Laboratories |
| **Sunquest Test Codes** | **IGE** |
| **Specimen** | Serum or plasma- no gel. Refer to specimen collection procedures for collection of diagnostic blood specimens. Lithium heparin, sodium heparin, citrate, and Potassium EDTA plasma are acceptable specimen types.**Patient** **Preparation:** None**Minimum draw volume:** 0.4 mL**Stability:** RT or 2-8 °C / 7 days, <-10 °C / 6 month. **Rejection criteria**: Unlabeled specimens, other than serum or heparinized plasma. Specimens collected using gel separators.**Preparation:** 1. Complete clot formation should take place before centrifugation.
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. Whole blood specimens should be centrifuged according to Specimen Processing procedures prior to analysis. See Processing Procedure Manual.
5. Transfer serum or plasma to a properly labeled Abbott sample cup or sendout tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.

Do not use gel separators as these samples have not been tested for acceptability.Do not induce foaming and avoid repeated freezing and thawing to preserve the integrity of the specimen from the time it is collected until the time it is assayed. |
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| **Materials** |

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| QUANTIA IgE Reagent | 06K42-40 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date**On-board: 20 days** |
| QUANTIA IgE Calibrator | 06K50-02 | **Store at:** 2 – 8 °C**Unopened and Opened and Stored Tightly capped:** Manufacturer’s printed expiration date. Allow to reach room temperature prior to pipetting aliquots.**Calibration Stability**: 30 days |

* Improper storage of reagents can affect assay performance
* Do not mix reagents for QUANTIA IgE between different kits. Use all reagents within the same kit lot together, or discard.
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| **Risk and Safety** | For *In Vitro Diagnostic* Use. For prescription use only.Reagents and are provided as a matched set and should not be interchanged with reagents from different lot numbers. Handle all patient specimens as if they were potentially infectious. |
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| **Preparing /Loading the Reagent Cartridges** | **STEP**  | **ACTION**  |
|  |  | Preparing Reagent R1:1. Obtain a small 20 mL cartridge
2. Label cartridge with Assay name, Lot number, R1 and date made
3. Pour one full 13 mL bottle of R1 into the small 20 mL cartridge
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|  |  | Preparing Reagent R21. Mix by inversion gently and completely, avoiding bubbles and foam
2. Obtain a 20mL cartridge
3. Label cartridge with Assay name, Lot number, R2 and date made
4. Pour 7mL of R2 into the 20mL Cartridge
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|  |  | Refer to the operating procedure for instructions on how to Configure and load the reagent in the following sections **Configuration of Non-barcoded Reagents and Diluents and** **Loading Non-barcoded Reagent** |
| **Calibration** |

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| Assay Range: | 25 to 1000 IU/mL |
| Reference Material: | QUANTIA IgE Calibrators |
| Suggested Calibration Levels: | **A** 50IU/mL 1 X 1 mL**B** 100 IU/mL 1 X 1 mL**C** 200 IU/mL 1 X 1 mL**D** 500 IU/mL 1 X 1 mL**E** 1000 IU/mL 1 X 1 mL |
| Calibration Scheme: | Five levels in duplicate |
| Calibration Frequency: | * Whenever a new lot number of reagents is used
* Whenever indicated by quality control results
* Whenever required by standard laboratory protocols
* Once every 960 hours
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| Analytical Measuring Range | 25 to 1000 IU/mLThe AMR is verified with each calibration using 6 levels of calibrator that span the full reportable range. Further studies are not necessary.  |
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|  | Refer to the calibration section of the CH 5.107 Abbott Architect c4000 Operating Procedure for programming and accepting calibrations. |

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| **Quality Control** | BioRad Immunology Controls Levels 1 and 3**Frequency:** * Two levels of controls must be run every 24 hours
* After loading a new set of reagents
* After calibration
* After any major maintenance/ repairs have been performed on the analyzer
* When indicated by QC results

**Storage and Stability**: Unopened: 2°- 8°C until manufacturer’s printed expiration dateOpen: 30 days when stored tightly capped at 2°- 8°C**Procedure**Controls are ready to use. Allow to reach room temperature prior to testing. Mix each level by gentle inversion before dispensing into individual sample cups for each level.**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](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.18-westgard-rules-in-chemistry.pdf) 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** | **Hemolysis, Icterus & Lipemia (HIL) Index Values:**

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See the product insert for a list of substances for which no significant interference was noted. |
| **Reference Range** |

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| Age | IgE IU/mL |
| <1 year | <15 |
| 1-5 years | <60 |
| 6 to 9 years | <90 |
| 10 to 15 years | <200 |
| 16+ years | <100 |

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| **Critical Values** | None defined. |
| **Limitations** | Linear range of detection: **25 to 1000 IU/mL**The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in open channel method results. Refer to your Abbott Architect® Operator’s Guide for the meaning of report flags and comments. Any report containing flags and/or comments must be resolved prior to reporting. There is no prozone interference for undiluted samples containing up to 26,000.0 IU/mL of IgE. Sample concentrations higher than 26,000.0 IU/mL have not been tested.As the limit of quantification of Quantia IgE is 25.0 IU/mL, it is not recommended to use this test for children less than 12 months of age. |
| **Dilutions** |

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| Max Auto Dilution: | 1:10 |
| Maximum Manual Dilution: | 1:50 |
| Diluent: | Saline |
| Manual Dilution: | Follow Abbott [Architect Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated and manual dilutions. The system will automatically calculate the concentration of the sample and report the result.  |

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| **Result Reporting** | * Results between **25 to 1000 IU/mL** without error messages are released
* Results below **25 IU/mL**: report as < **25 IU/mL** instead of the numerical value.
* Results >**1000 mcg/mL** are reported as the numerical result following a maximum autodilution of 1:10 or maximum manual dilution of 1:50
* Results that exceed the assay range following the maximum dilution are reported as >**50000 IU/mL**.
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. QUANTIA IgE Calibrator Instructions for Use, Distributed by Abbott Diagnostics, Abbott Park, IL, 60064 USA. February 2013.
2. QUANTIA IgE Reagent Instructions for Use, Distributed by Abbott Diagnostics, Abbott Park, IL, 60064 USA. February 2013.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Erin Bartos | 10/28/2020 | New Procedure on Abbott Architect |
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