



IBL-America

ACETYLCHOLINE RECEPTOR Ab Kit

In-vitro Diagnostic Use only



REF IB68400

IVD In-vitro Kit

INTENDED USE

The AChRab Assay is an *in-vitro-diagnostic* radioimmunoassay for the semi-quantitative determination of autoantibodies against the acetylcholine receptor in human serum. The AChRab assay is useful as an aid in the differential diagnosis of Myasthenia Gravis (MG) in conjunction with other clinical and laboratory findings.

SUMMARY AND EXPLANATION

Myasthenia Gravis (MG) is a skeletal muscle disorder characterized by muscular weakness. A good correlation is observed between anti-acetylcholine receptor (AChR) antibodies and muscle weakness in individual patients. Anti-AChR antibodies are present in approximately 90% of patients with MG. Anti-AChR antibodies could be: binding antibodies (multitudes of wide populations of antibodies directed to hydrophilic domains of receptors), blocking antibodies (preventing binding of acetylcholine to receptors) and modulating antibodies (accelerating endocytosis resulting in loss of receptors).

TEST PRINCIPLE

Anti-AChR antibodies are detectable by a radiobinding that is followed by precipitation of the antibodies. Patient specimens and references are incubated with detergent-solubilized fetal and adult AChRs labeled with ¹²⁵I- α -bungarotoxin. The resulting bound complexes of labeled AChRs and autoantibodies are then immunoprecipitated with anti-human IgG. After centrifugation, the supernatant is aspirated and the pellet containing labeled AChR/autoantibody-bound complexes is counted in a gamma counter. Counts are directly proportional to the amount of autoantibodies present.

MATERIALS

Materials Required But Not Supplied

- 12x75 mm polystyrene test tubes
- Pipettes calibrated to 5 μ L, 50 μ L, 100 μ L and 1000 μ L
- Vortex mixer
- Refrigerated centrifuge
- Refrigerator
- Test Tube Rack, polypropylene
- Freezer (Optional)
- Semi-log graph paper, or software for semi-log plots

Kit Components

| Symbol | Description | Part Number | QTY |
|----------------|--|-----------------|-----------------|
| | Anti-Acetylcholine Receptor Kit | ACRB4000 | 100 test |
| A1 - A6 | Standards (6 Levels) - Contains 0.0 (normal human serum); 0.2; 0.50; 1.25; 2.50; and 7.5 nmol/L Human anti- Acetylcholine Receptor in human serum; <0.1% NaN ₃ | ACRB4008A-F | 6x 0.20 mL |
| B | ¹²⁵ I-AChR - Contains ¹²⁵ I- α -Bungarotoxin-labeled human Acetylcholine Receptor; <1.8 μ Ci/vial [Lyophilized; Reconstitute with 2.8 mL Diluent C; use within 2 weeks] | ACRB4001 | 4x 2.8 mL |
| C | ¹²⁵ I-AChR Diluent - Contains 0.05M Tris Buffer with 1.5% Surfactant | ACRB4002 | 1x 12 mL |
| D | Positive Control -- Contains Human anti-Acetylcholine Receptor in human serum with <0.1% NaN ₃ ; See QC Certificate for acceptable range | ACRB4003 | 0.20 mL |
| E | Negative Control Cut Off Point - Contains human serum; with <0.1% NaN ₃ ; See QC Certificate for acceptable range | ACRB4004 | 0.20 mL |
| F | Goat Anti-Human IgG; contains <0.1% NaN ₃ | ACRB4005 | 22.0 mL |
| G | Normal Human Serum (for diluting test sera.) - Contains <0.1% NaN ₃ | ACRB4006 | 2 X 1.0 mL |
| H | Wash Buffer - Contains 0.05M Tris Buffer with 1.5% Surfactant | ACRB4007 | 2 x 110 mL |



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WARNINGS AND PRECAUTIONS

1. For in-vitro diagnostic use only. For professional use only.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. Do not interchange components from different lots. Do not use kit components beyond their expiration date.
4. Follow good laboratory practice and safety guidelines; Wear lab coat, disposable latex gloves and face shield or safety glasses when handling specimens, tracer and other hazardous reagents.
5. Reagents of this kit contain hazardous material and may cause eye and skin irritations. See MATERIALS SUPPLIED and labels for details. Material Safety Data Sheets for this product are available.
6. Chemicals and prepared or used reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
7. Note: Reagents in this assay contain sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush drains with generous amounts of cold water to prevent azide buildup. In addition, consult the manufacturing guideline, "Safety Management No. CDC-22, Decontamination of Laboratory Sink Drains to Remove Azide Salts" (Centers for Disease Control Atlanta, Georgia, April 30, 1976).
8. Radioactive Material – Not for Internal or External Use in Humans or Animals. This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a specific license issued by the Nuclear Regulatory Commission or issued by a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.
9. Radioactive materials should be confined to specifically designated, regularly monitored areas in the laboratory, restricted to authorized personnel. Use disposable labware and disposable absorbent bench covers. Always wear film badges, lab coats and disposable gloves. Wipe up all spills immediately, cleaning the contaminated area with a decontaminant and dispose the contaminated materials as radioactive waste.
10. **Caution:** All blood products should be treated as potentially infectious. Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No known test methods can offer total assurance that products derived from human blood will not transmit HBsAg, HCV, HIV1 or HIV2, or other potentially infectious agents. Therefore, these reagents and all patient's specimens should be handled as though capable of transmitting infection at Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the CDC/NIH manual – "Biosafety in Microbiology and Biomedical Laboratories", 1984 or latest edition.
11. **The following precautions should be observed in handling radioactive material.**
 - Store radioactive materials in a designated area.
 - Do not eat, drink, smoke, or apply cosmetics where radioactive materials are being handled.
 - Do not pipette by mouth.
 - When handling radioactive materials, wear gloves and wash hands thoroughly afterwards.
 - Cover working area with disposable absorbent paper.
 - Wipe up all spills immediately and thoroughly and dispose of the contaminated materials as radioactive waste.

STABILITY AND STORAGE

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The kits should be stored at 2-8°C. Do not freeze. Unopened kits are stable through the expiration date stated on the label.

SAMPLE COLLECTION

1. Qualified personnel using approved aseptic venipuncture techniques should collect a whole blood sample.
2. Serum should be separated from cells within one hour. Sera are stable up to 7 days refrigerated (freeze-thaw cycles may denature the antibody and cause spurious results.)
3. Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia is best avoided, but does not interfere with this assay. Samples appearing turbid should be centrifuged before testing to remove any particulate material.

PROCEDURAL NOTES

1. Controls or serum pools with varying Acetylcholine Receptor antibody levels (e.g. positive and negative) should be used for quality control.
2. Controls should be run along with patient samples. Chart the trends and analyze assay performance.
3. If control results show unusual trends or shifts outside the laboratory's limits of acceptability, patient results should not be reported and the assay should be repeated.

PREPARATION OF REAGENTS AND SAMPLES

Preparation of Tracer

Up to 30 minutes before use, reconstitute the lyophilized ¹²⁵I-Acetylcholine Receptor (B) with 2800 µL of ¹²⁵I-AChR diluent (C). Avoid foaming and check that all solids are dissolved. Use within 2 weeks of reconstitution; store at 2-8°C (Do Not Freeze after reconstitution).

Sample preparation

Calibrators and Controls are ready to use and need not be diluted. Samples that have values higher than the highest Calibrator should be diluted with Human Serum (Component G) and re-assayed.

PROCEDURE

- a) Bring all components and patient specimens to room temperature and mix well before use.
- b) Set up and label tubes for running the assay.
- c) Pipette **20 µL** of each Standard (A1-A6) in duplicate into their respective tubes.
- d) Pipette **20 µL** of each control (D, E) in duplicate into their respective tubes.
- e) Pipette **20 µL** of the patient specimen(s) into their respective tubes.
- f) Pipette **100 µL** of the reconstituted ¹²⁵I-Acetylcholine Receptor Tracer into all of the tubes, **including two tubes for measurement of Total Counts (TC). Set these two Total Counts tubes aside until step m) below** and Vortex the remaining tubes.
- g) Incubate tubes at room temperature (22- 28°C) for **two (2) hours**.
- h) Pipette **200 µL** of anti-human IgG (F) into all tubes and Vortex gently. Incubate at room temperature (22-28°C) for **30 minutes**.
- i) Add **1000 µL** of Wash Buffer (H) to each tube. Vortex each tube for 20 seconds and then centrifuge all tubes for **20-30 minutes at 3500 rpm** at a temperature of 2-8°C.
- j) Carefully decant or aspirate the supernatants without disturbing the pellets.
- k) Add **1000 µL** of Wash Buffer (H) to each tube. Vortex each tube for 20 seconds and then centrifuge all tubes for **20-30 minutes at 3500 rpm** at a temperature of 2-8°C.
- l) Carefully decant or aspirate the supernatants without disturbing the pellets.
- m) Within 24 hours after decanting or aspiration, determine the CPM for each tube, including the two Total Activity tubes that were set aside in step f), for one (1) minute in a gamma counter set for measuring ¹²⁵I.

CALCULATION OF RESULTS

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For each run, a standard curve must be calculated from the mean CPM of each of the six standards (A1-A6). Always refer to vial labels for exact concentrations.

Typical Calibration Data:

| Standard | Anti-AChR (nmol/L) | Mean CPM |
|----------|--------------------|----------|
| A1 | 0 | 647 |
| A2 | 0.20 | 2513 |
| A3 | 0.50 | 3841 |
| A4 | 1.25 | 8789 |
| A5 | 2.50 | 11037 |
| A6 | 7.50 | 18544 |

For each standard (A1-A6), calculate the percent binding (%B/TC or %Binding/Total Counts) as follows:

$$\% \text{ B/TC} = \frac{\text{Mean CPM (Standard tubes)}}{\text{Mean CPM (Total Counts tubes)}} \times 100$$

Appropriate computer assisted data reduction programs may be used to generate the required non-linear standard curve by plotting the calculated %B/TC of each standard on the ordinate against the standard concentration obtained from the respective vial labels on the abscissa. For example, data presented here was obtained using an FPL curve fit program. The concentration of the unknown samples or diluted samples can then be read directly from the standard curve.

NOTE: Dilute high patient samples with Reagent G, Normal Human Serum.

Patient samples with values > 7.5 nmol/L should be diluted further and re assayed. Multiple dilutions may be required for very high positive samples. The calculated value is multiplied by any sample dilution to obtain corrected value.

NOTE: Low samples (or diluted samples) with CPM **between** the 1st standard (A1) and 2nd standard (A2) can be approximated by the formula:

$$\text{Value of unknown} = \frac{\text{CPM (unknown)}}{\text{CPM (2nd Std.)}} \times \text{Value of the 2nd Std.}$$

INTERPRETATION OF RESULTS

The results themselves should not be the only reason for any therapeutic decisions. Results must be correlated to other clinical observations.

Typical Interpretation:

- < 0.25 nmol/L: Negative
- 0.25 - 0.40 nmol/L: Equivocal (Physician may want to re-test the patient after two weeks)
- >0.40 nmol/L: Positive



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QUALITY CONTROL

The test results are only valid if the test has been performed following the instructions. The user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable local, state, and federal regulations. Positive and Negative Control sera are supplied with the kit. The Negative and Positive controls validate the assay at the critical levels to ensure test performance, test integrity and operator reliability. Good laboratory practice dictates running the positive and negative controls each time the kit is used. This test is only valid if the range for Positive Control (D) and Negative Control (E) complies with the respective range indicated on the Quality Control Certificate enclosed to each test kit! If the results of the positive and/or negative control are not within the range, the test results are invalid and the assay should be rerun. Warning: If QC results are "out of range" or invalid, the results must not be reported. Each laboratory should use known samples as further controls. Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations.

LIMITATIONS

1. The values obtained from this assay are intended to be an aid to diagnosis only. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated. Results must be correlated with other clinical observations.
2. A negative patient result does not rule out the presence of MG disease.
3. Only if test instructions are rigidly followed will optimum results be achieved.
4. Each physician must interpret the results in light of the patient's history, physical findings and other diagnostic procedures.
5. Reproducible results depend on careful pipetting, observation of incubation periods and temperature, caution during decantation, and thorough mixing of all prepared solutions.
6. Instructions for use of all appropriate instruments are to be observed.
7. Performance has not been tested with on the pediatric population.

EXPECTED VALUES

Serum samples from a total of 72 apparently healthy asymptomatic male and female blood donors age 18 to 56 years from a blood bank were assayed to determine the expected values and cutoff for the test. Range of normal healthy blood donor values are shown below. The cutoff is calculated as mean + 2 S.D. and is 0.25 nmol/L. Each laboratory should establish its own range of normal values.

| | FEMALES | MALES |
|----------------|---------|-------|
| AVERAGE | 0.05 | 0.09 |
| SD | 0.043 | 0.062 |
| CV | 93.1% | 66.0% |
| MAX | 0.14 | 0.39 |
| MIN | 0.00 | 0.00 |
| N | 17 | 55 |

PERFORMANCE CHARACTERISTICS

Analytical Specificity (Cross Reactivity)

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No cross-reactivity found in sera containing Nucleolar, RF, SM/RNP, dsDNA, Homogeneous, SSA, Speckled, or SSB autoantibodies.

Interferences by Serum Components

Hemoglobin, Bilirubin and Triglycerides were evaluated for possible interferences in the AChRAb using three serum pools of different concentrations. Hemoglobin was tested at concentrations between 1.9 and 400 mg/dL, Bilirubin between 1.25 and 50 mg/dL and Triglycerides between 25 and 3,000 mg/dL.

No significant interference was seen related to the addition of Hemoglobin, Bilirubin, or Triglycerides.

Analytical Sensitivity (Limit of Blank)

Analytical sensitivity was calculated from the mean of the CPM of Zero Calibrator (A1) plus 2 SD of 20 replicate analyses. The value was found to be 0.058 nmol/L.

Functional Sensitivity (Limit of Quantitation)

Six serum samples with AChRAb concentrations near the bottom end of the assay of were measured in quadruplicate over 5 days. The mean value and coefficient of variation was calculated. The lowest AChRAb concentration measured with a coefficient of variation below 20% was 0.11 nmol/L.

Precision

Intra Assay

To evaluate the Intra Assay reproducibility, two sets of serum pools were run by two different technicians.

The first set of three sera was run in replicates of 16 by two technicians on one day.

The second set of Intra Assay results was performed by one technician over multiple days using seven serum pools run in replicates of 21 each.

The results of the assays are shown in the tables below.

| Tech 1 | MEAN (nmol/L) | SD (nmol/L) | CV (%) | Tech 2 | MEAN (nmol/L) | SD (nmol/L) | CV (%) |
|--------|---------------|-------------|--------|--------|---------------|-------------|--------|
| S1 | 0.37 | 0.033 | 8.96% | S1 | 0.46 | 0.028 | 6.14% |
| S2 | 1.67 | 0.189 | 11.26% | S2 | 1.65 | 0.201 | 12.18% |
| S3 | 6.45 | 0.187 | 2.91% | S3 | 5.91 | 0.195 | 3.30% |

| | Serum 1 (nmol/L) | Serum 2 (nmol/L) | Serum 3 (nmol/L) | Serum 4 (nmol/L) | Serum 5 (nmol/L) | Serum 6 (nmol/L) | Serum 7 (nmol/L) |
|---------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Mean | 0.52 | 0.67 | 0.92 | 1.54 | 2.02 | 4.22 | 6.66 |
| SD | 0.041 | 0.063 | 0.037 | 0.084 | 0.088 | 0.130 | 0.175 |
| CV (%) | 7.77% | 9.31% | 4.08% | 5.47% | 4.36% | 3.08% | 2.63% |

Inter Assay

The inter assay variation of 7 serum samples covering the standard curve of the AChRAb assay was estimated using one kit lot in 15 assay runs (one or two assays a day in duplicate) performed in various labs at the manufacturer's facility with multiple technicians.

| | Serum 1 (nmol/L) | Serum 2 (nmol/L) | Serum 3 (nmol/L) | Serum 4 (nmol/L) | Serum 5 (nmol/L) | Serum 6 (nmol/L) | Serum 7 (nmol/L) |
|---------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Mean | 0.46 | 0.78 | 1.00 | 1.50 | 2.11 | 4.30 | 6.81 |
| SD | 0.047 | 0.058 | 0.092 | 0.136 | 0.208 | 0.205 | 0.287 |
| CV (%) | 10.3% | 7.5% | 9.2% | 9.1% | 9.9% | 4.8% | 4.2% |



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Lot to Lot Reproducibility

Several Serum Pools were diluted to low values and assayed in duplicate with three lots of reagents. C.V.'s ranged from 3.0% (Mean = 1.297 nmol/L) to 16.6% (Mean = 0.219 nmol/L) The pooled C.V. (calculated as the square root of the average of the squared C.V. for all samples across all three lots) was 8.6%.

| Sample | INTERLOT RESULTS (nmol/L) | | | | |
|-------------|---------------------------|---------|---------|-----------|-------|
| | Lot 277 | Lot 165 | Lot 166 | Mean | CV(%) |
| NB1032-164A | 0.21 | 0.26 | 0.19 | 0.219 | 16.6% |
| NB1032-164B | 0.17 | 0.19 | 0.16 | 0.173 | 8.8% |
| NB1032-164C | 0.35 | 0.38 | 0.43 | 0.387 | 10.5% |
| NB1032-164D | 0.31 | 0.34 | 0.32 | 0.322 | 3.9% |
| NB1032-164E | 0.55 | 0.57 | 0.62 | 0.577 | 6.7% |
| NB1032-164F | 0.44 | 0.47 | 0.53 | 0.477 | 9.2% |
| NB1032-164G | 0.69 | 0.69 | 0.75 | 0.708 | 5.1% |
| NB1032-164H | 1.29 | 1.27 | 1.34 | 1.297 | 3.0% |
| NB1032-164I | 1.14 | 1.23 | 1.27 | 1.208 | 5.5% |
| | | | | Pooled CV | 8.6% |

Linearity

Two serum samples having different acetylcholine receptor antibody levels were serially diluted with the Normal Serum Diluent (G) and the acetylcholine receptor antibody levels in the diluted samples was assayed. The results obtained with individual serum samples are presented in the table below. Multiple dilutions were performed for each sample. Each dilution was measured in duplicates in one assay run. The relation between concentration and dilution of sera did not significantly deviate from linearity over the concentration range studied.

| Serum 1 Dilution | Measured (nmol/L) | Recovery (%) | Serum 2 Dilution | Measured (nmol/L) | Recovery (%) |
|------------------|-------------------|--------------|------------------|-------------------|--------------|
| neat | >8.5 | - | neat | 0.72 | 106% |
| neat | >8.5 | - | neat | 0.64 | 94% |
| 1:1.2 | >8.5 | - | 1:1.2 | 0.54 | 95% |
| 1:1.2 | 8.12 | 92% | 1:1.2 | 0.49 | 86% |
| 1:1.4 | 7.63 | 101% | 1:1.4 | 0.54 | 111% |
| 1:1.4 | 7.56 | 100% | 1:1.4 | 0.40 | 82% |
| 1:1.8 | 6.61 | 112% | 1:1.8 | 0.39 | 103% |
| 1:1.8 | 5.99 | 101% | 1:1.8 | 0.35 | 93% |
| 1:2 | 6.40 | 120% | 1:2 | 0.28 | 82% |
| 1:2 | 5.88 | 111% | 1:2 | 0.30 | 88% |
| 1:3 | 3.95 | 112% | 1:3 | 0.24 | 106% |
| 1:3 | 3.47 | 98% | 1:3 | 0.21 | 96% |
| 1:4 | 2.80 | 105% | 1:4 | 0.14 | 82% |
| 1:4 | 2.76 | 104% | 1:4 | 0.15 | 88% |
| 1:8 | 1.36 | 102% | 1:8 | 0.10 | 118% |
| 1:8 | 1.17 | 88% | 1:8 | 0.10 | 118% |



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Recovery

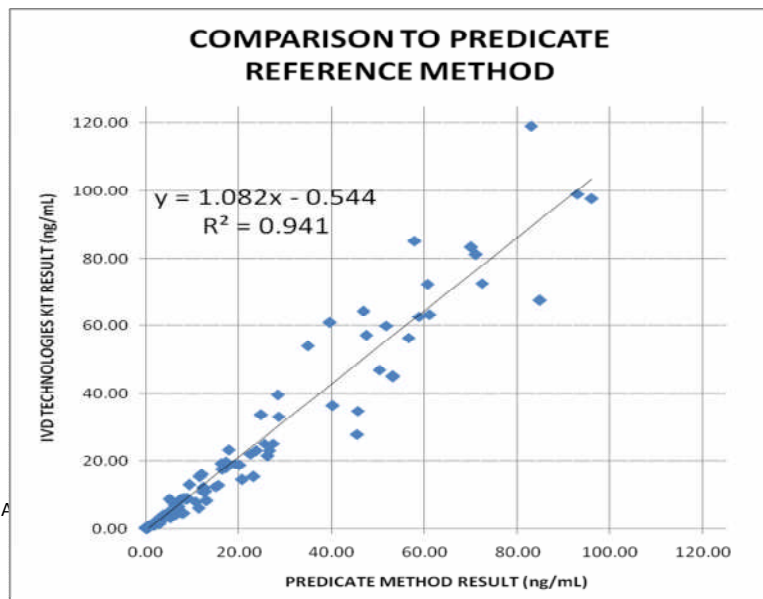
Different amounts of acetylcholine receptor antibodies from three sera pools were added to a high concentration serum pool to yield various initial acetylcholine receptor antibody concentrations. Each sample (non spiked and spiked) was assayed in quadruplicates in one run. Acetylcholine receptor antibody concentrations were measured and the percentage recovery rates were calculated. The mean recovery of acetylcholine receptor antibodies ranged from 93.8 % to 105.3 %. The Expected Values and Recovered Values are shown in the table below. The relation between expected and measured concentration of sera did not significantly deviate over the range of 0.86 to 4.6 nmol/L.

| SPIKE | VALUES | | |
|-------|----------|-----------|---------|
| | EXPECTED | RECOVERED | PERCENT |
| A | 0.86 | 0.81 | 94.1% |
| B | 1.13 | 1.09 | 96.6% |
| C | 1.29 | 1.21 | 93.8% |
| D | 1.55 | 1.49 | 96.2% |
| E | 2.08 | 2.13 | 102.3% |
| F | 2.42 | 2.36 | 97.4% |
| G | 3.69 | 3.89 | 105.3% |
| H | 4.15 | 4.27 | 102.9% |
| I | 4.64 | 4.85 | 104.6% |

Comparison Study

The IVD AChRab test was used to measure acetylcholine receptor antibodies in 149 samples from myasthenia gravis patients and patient samples sent to a laboratory to be tested for suspected disease and samples sent for testing for other conditions. The samples were obtained from two laboratories in the U.S. and Germany. The positive samples above the highest Calibrator value were diluted in Normal Human Serum (Component G) and re assayed and the values corrected for dilution. This was done until the diluted samples fell within the Calibrator curve for both the predicate test and the IVD test.

The results were compared by linear regression and are presented in the figures and tables below. A good correlation was observed between the IVD results (y) and the reference RIA test results (x) for the sera studied (see table below). The tables show the comparison of the quantitative results for the serum samples. Therefore, the clinical sensitivity and the clinical specificity of the IVD AChRab can be calculated.





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Positive and Negative Agreement with Predicted Assay (Summary)

| | | Predicate Assay | | | |
|-------------------|-----------|-----------------|-----------|----|-------|
| | | + | Equivocal | - | Total |
| IVD AChR Ab Assay | + | 96 | 1 | 0 | 97 |
| | Equivocal | 0 | 0 | 2 | 2 |
| | - | 1 | 3 | 28 | 32 |
| | Total | 97 | 4 | 30 | 131 |

Treating equivocal results as positive:

Positive agreement = 96.0% with 95% CI: 90.2% to 98.4%

Negative agreement = 93.3% with 95% CI: 78.7% to 98.2%

Overall agreement = 95.4% with 95% CI: 90.4% to 97.9%

Treating equivocal results as negative:

Positive agreement = 99.0% with 95% CI: 94.4% to 99.8%

Negative agreement = 97.1% with 95% CI: 85.1% to 99.5%

Overall agreement = 98.5% with 95% CI: 94.6% to 99.6%

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