Elecsys ACTH

English

System information
For cobas e 411 analyzer: test number 080
For MODULAR ANALYTICS E170, cobas e 601 and cobas e 602
analyzers: Application Code Number 162

Intended use
Immunnoassay for the in vitro quantitative determination of adrenocorticotropic hormone (ACTH) in human EDTA plasma. The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Summary
Adrenocorticotropic hormone (ACTH) or corticotropin is a peptide hormone consisting of 39 amino acids. It is produced in the anterior pituitary of the brain as part of the precursor molecule pro-opiomelanocortin (POMC). Tissue-specific cleavage results in ACTH and a range of related peptides. ACTH stimulates formation and secretion of glucocorticoids (especially cortisol) by the adrenal cortex.

The glucocorticoid production is regulated by various factors. After stimulation (e.g. by physical effort or by the internal body clock), the hypothalamus secretes CRH (corticotropin releasing hormone). CRH acts on the pituitary, which in turn synthesizes and secretes ACTH. Finally, ACTH stimulates secretion of the glucocorticoids by the adrenals. High concentrations of glucocorticoids in the blood inhibit secretion of CRH and ACTH via a negative feedback mechanism. ACTH concentrations show a diurnal variation with high levels in the morning and low levels in the evening. Therefore, as with cortisol, it is important to know the collection time of the plasma sample for interpretation of the results.

Plasma ACTH measurements are useful in the differential diagnosis of Cushings's disease (ACTH hypersecretion), autonomous ACTH producing pituitary tissue (e.g. Nelson's syndrome), hypopituitarism with ACTH deficiency and ectopic ACTH syndrome. In addition to cortisol measurements, ACTH determinations can be used together with suppression or stimulation tests to diagnose the origin of glucocorticoid overproduction. Similarly, ACTH measurements can be employed to facilitate differential diagnosis of adrenocortical insufficiency (Addison's disease).

ACTH not produced by the pituitary gland is known as ectopic ACTH; this is often associated with small cell carcinoma of the lung. In rare cases ectopic ACTH can be caused by thymic tumors, pancreatic adenocarcinomas, or bronchial carcinoids. These tumors often secrete ACTH precursors (POMC and pro-ACTH).

The Elecsys ACTH assay employs two monoclonal antibodies specific for ACTH (9-12) and for the C-terminal region (36-39).

Due to common antigenic structure, the antibodies recognize intact biologically active ACTH 1-39 and the ACTH precursors POMC and pro-ACTH.

Test principle
Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 50 μL of sample, a biotinylated monoclonal ACTH-specific antibody, and a monoclonal ACTH-specific antibody labeled with a ruthenium complex react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode or e-barcode.

Reagents - working solutions

The reagent rackpack is labeled as ACTH.

- Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL:
  Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- Anti-ACTH-Ab–biotin (gray cap), 1 bottle, 8 mL:
  Biotinylated monoclonal anti-ACTH antibody (mouse) 0.3 mg/L; MES buffer 50 mmol/L, pH 6.2; preservative.
- Anti-ACTH-Ab–Ru(bpy)(II) (black cap), 1 bottle, 8 mL:
  Monoclonal anti-ACTH antibody (mouse) labeled with ruthenium complex 0.3 mg/L; MES buffer 50 mmol/L, pH 6.2; preservative.
- MES = 2-morpholinoethane sulfonic acid

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents. Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal. Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

PRODUCT SPECIFICATION SHEET

Elecsys ACTH® Test Code: 03255751500

Measurement Principle: Immunoassay

Description:

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents. Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal. Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Safety data sheet available for professional user on request.
Electsys ACTH

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336
Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling
The reagents in the kit have been assembled into a ready-for-use unit that cannot be separated.
All information required for correct operation is read in from the respective reagent barcodes.

Storage and stability
Store at 2-8 °C.
Do not freeze.
Store the Electsys reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

<table>
<thead>
<tr>
<th>Stability:</th>
</tr>
</thead>
<tbody>
<tr>
<td>unopened at 2-8 °C</td>
</tr>
<tr>
<td>after opening at 2-8 °C</td>
</tr>
<tr>
<td>on the analyzers</td>
</tr>
<tr>
<td>up to the stated expiration date</td>
</tr>
<tr>
<td>12 weeks</td>
</tr>
<tr>
<td>4 weeks</td>
</tr>
</tbody>
</table>

Specimen collection and preparation
Only the specimens listed below were tested and found acceptable.
K₅- and K₂-EDTA plasma, collected using siliconized glass tubes or plastic tubes as ACTH adsorbs to non-siliconized glass tubes and thereby reduces sample ACTH values.² Do not use other types of plasma samples.

Criterion for K₂-EDTA plasma: slope 0.85-1.15 for method comparison vs K₅-EDTA plasma.

Only use pre-cooled sampling vials. After drawing the blood, put the vials immediately on ice. Use a cooled centrifuge to separate the plasma. Measure samples immediately or freeze them at -20 °C (± 5 °C).
Stable for 3 hours at 2-8 °C followed by 2 hours at 20-25 °C, 10 weeks at -20 °C (± 5 °C). Freeze only once.
The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.
Centrifuge samples containing precipitates before performing the assay. Do not use heat-inactivated samples.
Do not use samples and controls stabilized with azide.
Ensure the samples, calibrators and controls are at 20-25 °C prior to measurement.
Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/measured within 2 hours.
Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

Materials provided
See “Reagents – working solutions” section for reagents.

Materials required (but not provided)
- [REF] 03255760190, ACTH CalSet, for 4 x 1.0 mL
- [REF] 05341787190, PreciControl Multimarker, for 6 x 2.0 mL
- [REF] 05341787160, PreciControl Multimarker, for 6 x 2.0 mL (for USA)
- General laboratory equipment
- MODULAR ANALYTICS E170 or cobas e analyzer

Additional materials for the cobas e 411 analyzer:
- [REF] 11662988122, ProCell, 6 x 380 mL system buffer

- [REF] 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- [REF] 11930346122, Elecsys SysWash, 1 x 500 mL wash additive
- [REF] 11933159001, Adapter for SysClean
- [REF] 11706802001, AssayCup, 60 x 60 reaction cups
- [REF] 11706799001, AssayTip, 30 x 120 pipette tips
- [REF] 11800507001, Clean-Liner

Additional materials for MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers:
- [REF] 04880304190, ProCell M, 2 x 2 L system buffer
- [REF] 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- [REF] 03023141001, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
- [REF] 03005712190, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
- [REF] 03004999190, PreClean M, 5 x 600 mL detection cleaning solution
- [REF] 12102137001, AssayTip/AssayCup, 48 magazines x 84 reaction cups or pipette tips, waste bags
- [REF] 03023150001, WasteLiner, waste bags
- [REF] 03027651001, SysClean Adapter M

Additional materials for all analyzers:
- [REF] 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution
- [REF] 11298500160, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution (for USA)

Assay
For optimal performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.
Resuspension of the microparticles takes place automatically prior to use.
Read in the test-specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.
MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers: PreClean M solution is necessary.
Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Calibration
Traceability: This method has been standardized gravimetrically with synthetic ACTH produced at Roche.
Every Electsys reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.
Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).
Calibration interval may be extended based on acceptable verification of calibration by the laboratory.
Renewed calibration is recommended as follows:
- after 1 month (28 days) when using the same reagent lot
- after 7 days (when using the same reagent kit on the analyzer)
- as required: e.g. quality control findings outside the defined limits

Quality control
For quality control, use PreciControl Multimarker.
In addition, other suitable control material can be used.
Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent lot, and following each calibration.
**Elecsys ACTH**

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits. If necessary, repeat the measurement of the samples concerned. Follow the applicable government regulations and local guidelines for quality control.

**Calculation**

The analyzer automatically calculates the analyte concentration of each sample either in pg/mL, pmol/L or ng/L (selectable).

Conversion factors:  
- pg/mL x 0.2202 = pmol/L  
- pmol/L x 4.541 = pg/mL

**Limitations - interference**

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

**Endogenous substances**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>≤ 428 pmol/L or ≤ 25 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>≤ 0.25 mmol/L or ≤ 0.4 g/dL</td>
</tr>
<tr>
<td>Intralipid</td>
<td>≤ 1500 mg/dL</td>
</tr>
<tr>
<td>Biotin</td>
<td>≤ 246 nmol/L or ≤ 60 ng/mL</td>
</tr>
<tr>
<td>Rheumatoid factors</td>
<td>≤ 400 IU/mL</td>
</tr>
</tbody>
</table>

Criterion: For concentrations of 1.00-20 pg/mL the deviation is ± 3 pg/mL. For concentrations > 20-2000 pg/mL, the deviation is ± 15 %. Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

There is no high-dose hook effect at ACTH concentrations up to 1 x 10^6 pg/mL.

In vitro tests were performed on 17 commonly used pharmaceuticals. No interference with the assay was found.

However, under ACTH 1-24 medication, ACTH measurement is not recommended, due to negative interference with the sandwich assay. In rare cases, interference due to extremely high titters of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

**Limits and ranges**

**Measuring range**

1.00-2000 pg/mL or 0.220-440 pmol/L (defined by the Lower Detection Limit and the maximum of the master curve). Values below the Lower Detection Limit are reported as < 1.00 pg/mL or < 0.220 pmol/L. Values above the measuring range are reported as ≥ 2000 pg/mL or ≥ 440 pmol/L.

**Lower limits of measurement**

- Lower Detection Limit of the test: 1.00 pg/mL or 0.220 pmol/L
  - The Lower Detection Limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 21).

**Dilution**

Not necessary due to the broad measuring range.

**Expected values**

Studies with the Elecsys ACTH assay using plasma samples from 354 apparently healthy adults gave the following results (5th-95th percentile): 7.2-63.3 pg/mL (1.6-13.9 pmol/L). The plasma samples were drawn between 7-10 a.m.

ACTH concentrations vary considerably depending on physiological conditions. Therefore, ACTH results should always be evaluated together with simultaneously measured cortisol concentrations.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

**Specific performance data**

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

**Precision**

Precision was determined using Elecsys reagents and pooled human plasma in a modified protocol (EP5-A) of the CLSI (Clinical and Laboratory Standards Institute); 6 times daily for 10 days (n = 60); repeatability on MODULAR ANALYTICS E170 analyzer, n = 21. The following results were obtained:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th>Intermediate precision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pg/mL</td>
<td>pmol/L</td>
<td>pmol/L</td>
<td>%</td>
</tr>
<tr>
<td>HP¹ 1</td>
<td>5.12</td>
<td>1.13</td>
<td>0.167</td>
<td>3.2</td>
</tr>
<tr>
<td>HP 2</td>
<td>76.9</td>
<td>16.9</td>
<td>1.02</td>
<td>2.25</td>
</tr>
<tr>
<td>HP 3</td>
<td>1439</td>
<td>317</td>
<td>17.1</td>
<td>3.77</td>
</tr>
</tbody>
</table>

**Repeatability**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th>Intermediate precision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pg/mL</td>
<td>pmol/L</td>
<td>pmol/L</td>
<td>%</td>
</tr>
<tr>
<td>HP 1</td>
<td>4.9</td>
<td>1.09</td>
<td>0.066</td>
<td>5.4</td>
</tr>
<tr>
<td>HP 2</td>
<td>76.1</td>
<td>16.8</td>
<td>2.67</td>
<td>3.5</td>
</tr>
<tr>
<td>HP 3</td>
<td>1444</td>
<td>318</td>
<td>53.6</td>
<td>11.8</td>
</tr>
</tbody>
</table>

**Intermediate precision**

Precision was determined using Elecsys reagents and controls in a protocol (EP5-A2) of the CLSI (Clinical and Laboratory Standards Institute); 2 runs per day in duplicate each for 21 days (n = 84). The following results were obtained:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th>Intermediate precision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pg/mL</td>
<td>pmol/L</td>
<td>pmol/L</td>
<td>%</td>
</tr>
<tr>
<td>PC MM¹</td>
<td>51.7</td>
<td>11.4</td>
<td>0.114</td>
<td>2.2</td>
</tr>
<tr>
<td>PC MM2</td>
<td>1070</td>
<td>236</td>
<td>11.6</td>
<td>5.57</td>
</tr>
</tbody>
</table>

d) PC MM = PreciControl Multimarker

---

2024-03, V 13.0 English 3 / 5
Elecsys ACTH

MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean concentration (pg/mL)</th>
<th>SD</th>
<th>CV</th>
<th>Intermediate precision (pmol/L)</th>
<th>SD</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC MM1</td>
<td>52.5</td>
<td>11.6</td>
<td>1.91</td>
<td>4.2</td>
<td>0.421</td>
<td>3.6</td>
</tr>
<tr>
<td>PC MM2</td>
<td>1170</td>
<td>258</td>
<td>28.4</td>
<td>4.2</td>
<td>6.25</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Method comparison

A comparison of the Elecsys ACTH assay (y) with a commercially available ACTH test (x) using clinical samples gave the following correlations (pg/mL):

Number of samples measured: 180

Passing/Bablok

\[ y = 1.08x + 1.23 \]

\( r = 0.898 \)

The sample concentrations were between 5.0 and 941 pg/mL or 1.1 and 207 pmol/L.

Specificity/cross-reactivity

The Elecsys ACTH two-site immunocassay measures intact ACTH 1-39. When ACTH fragments or peptides were added to a patient’s plasma sample with defined ACTH concentration, no interference was observed with ACTH 1-10, ACTH 11-24, beta-MSH, and beta-Endorphin.

ACTH fragments (ACTH 1-17, ACTH 1-24, ACTH CLIP 18-39, ACTH 22-39, alpha-MSH 1-13) can bind to one of the antibodies and thereby negatively interfere with the sandwich formation and lead to lower ACTH values as shown in the following table:

<table>
<thead>
<tr>
<th>Cross reactant</th>
<th>Concentration of cross reactant (pg/mL)</th>
<th>Apparent ACTH (pg/mL)</th>
<th>Change in ACTH concentration (pg/mL)</th>
<th>Cross-reactivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None; reference</td>
<td>0</td>
<td>44.1</td>
<td>not applicable</td>
<td>not applicable</td>
</tr>
<tr>
<td>ACTH 1-17</td>
<td>50000</td>
<td>10.6</td>
<td>-33.5</td>
<td>-0.07</td>
</tr>
<tr>
<td></td>
<td>5000</td>
<td>36.9</td>
<td>-7.2</td>
<td>-0.14</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>42.6</td>
<td>-1.5</td>
<td>-0.31</td>
</tr>
<tr>
<td>ACTH 1-24</td>
<td>50000</td>
<td>10.2</td>
<td>-33.9</td>
<td>-0.07</td>
</tr>
<tr>
<td></td>
<td>5000</td>
<td>37.9</td>
<td>-6.2</td>
<td>-0.12</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>42.5</td>
<td>-1.6</td>
<td>-0.32</td>
</tr>
<tr>
<td>ACTH 18-39</td>
<td>50000</td>
<td>2.0</td>
<td>-42.1</td>
<td>-0.08</td>
</tr>
<tr>
<td></td>
<td>5000</td>
<td>14.9</td>
<td>-29.2</td>
<td>-0.58</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>37.0</td>
<td>-7.1</td>
<td>-1.42</td>
</tr>
<tr>
<td>ACTH 22-39</td>
<td>50000</td>
<td>0.00</td>
<td>-44.1</td>
<td>-0.09</td>
</tr>
<tr>
<td></td>
<td>5000</td>
<td>6.3</td>
<td>-37.8</td>
<td>-0.76</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>29.4</td>
<td>-14.7</td>
<td>-2.94</td>
</tr>
<tr>
<td>alpha-MSH</td>
<td>50000</td>
<td>12.3</td>
<td>-31.8</td>
<td>-0.06</td>
</tr>
<tr>
<td></td>
<td>5000</td>
<td>34.3</td>
<td>-9.8</td>
<td>-0.20</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>41.3</td>
<td>-2.8</td>
<td>-0.56</td>
</tr>
</tbody>
</table>

Under ACTH 1-24 medication, ACTH measurement is not recommended. POMC (partially purified from an adenoma cell line) showed an approximately 1.8% cross-reactivity at 1560 pmol/L which is approximately 40 times the physiological concentration of ACTH precursors in circulation.

References


For further information, please refer to the appropriate operator’s manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country). A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

- CONTENT
  - Contents of kit
- SYSTEM
  - Analyzers/Instruments on which reagents can be used
- REAGENT
  - Reagent
- CALIBRATOR
  - Calibrator
- VOLUME
  - Volume after reconstitution or mixing
- GTIN
  - Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.
Elecsys ACTH