December 21, 2018

Axis-Shield Diagnostics Limited
Claire Dora
Regulatory Affairs Manager
Luna Place, The Technology Park
Dundee, Scotland DD2 1XA
UK

Re: K182012
Trade/Device Name: ADVIA Centaur® Calcitonin (CALCT) assay
Regulation Number: 21 CFR 862.1140
Regulation Name: Calcitonin test system
Regulatory Class: Class II
Product Code: JKR
Dated: November 29, 2018
Received: December 3, 2018

Dear Claire Dora:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
**K182012**

Device Name
ADVIA Centaur® Calcitonin (CALCT) assay

Indications for Use *(Describe)*
The ADVIA Centaur® Calcitonin (CALCT) assay is for in vitro diagnostic use in the quantitative measurement of calcitonin in human serum using the ADVIA Centaur XP system. Calcitonin measurement is used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# ADVIA Centaur Calcitonin (CALCT) Assay
# 510(k) Summary

Created: 19th December 2018

# ADVIA Centaur Calcitonin (CALCT) Assay 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K182012

**Submission correspondent:**

Dr. Claire Dora
Regulatory Affairs Manager Axis-Shield Diagnostics Ltd.
The Technology Park,
Dundee, DD2 1XA,
UK
Tel: +44(0)1382 422000

**Device Name:**
ADVIA Centaur® Calcitonin assay

**Reagents:**
Classification Name: Radioimmunoassay, Calcitonin **Trade Name:** ADVIA Centaur® Calcitonin (CALCT) assay Common Name: Calcitonin
Governing Regulation: 862.1140 Device Classification: Class II Classification Panel: Chemistry Product Code: JKR

**Legally marketed device to which equivalency is claimed:**
Roche Elecsys/Cobas® Calcitonin (k132828)

**Intended Use of Device:**
The ADVIA Centaur® Calcitonin (CALCT) assay is for in vitro diagnostic use in the quantitative measurement of calcitonin in human serum using the ADVIA Centaur XP system. Calcitonin measurement is used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism.

**Device Summary:**
The ADVIA Centaur CALCT Assay Kit (100-Tests) consists of 1 ReadyPack containing ADVIA Centaur CALCT Lite Reagent and Solid Phase reagent, and one set of Calibrators (1 vial each of Low and High, with fill volume of 2 mL each).
ADVIA Centaur CALCT Calibrator Assigned Value Card and barcode labels and ADVIA Centaur CALCT Master Curve Card are also included in the kit.

**Principles of the Device:**

The ADVIA Centaur CALCT assay is a fully automated, two-step immunoassay using direct chemiluminescent technology. The assay utilizes an acridinium- ester-labeled recombinant antibody as the Lite Reagent. The Solid phase consists of anti-calcitonin mouse monoclonal antibody-coated paramagnetic microparticles.
The system automatically performs the following steps:

- Dispenses 100 µL of sample into a cuvette.
- Dispenses 120 µL of Solid Phase and incubates the mixture for 18 minutes at 37°C.
- Separates the Solid Phase from the mixture, aspirates the unbound reagent.
- Washes the cuvettes and resuspends the particles in ADVIA Centaur Wash 1.
- Dispenses 100 µL of Lite Reagent into the cuvette and incubates for 18 minutes at 37°C.
- Separates the Solid Phase from the mixture, aspirates the unbound reagent.
- Washes cuvettes in ADVIA Centaur Wash 1.
- Dispenses 300 µL each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction.
- Calculates the results from the relative light units (RLU) generated using a stored master, curve, and reports in pg/mL (pmol/L).

A direct relationship exists between the amount of calcitonin present in the patient sample and the amount of relative light units (RLUs) detected by the system.
The system washes the reagent probe with ADVIA Centaur APW1 or ADVIA Centaur PW4 to mitigate potential interference between the ADVIA Centaur CALCT assay and other assays.

**Comparison of Technological Characteristics:**

The ADVIA Centaur CALCT assay and the Roche Elecsys/Cobas® Calcitonin assay are both automated immunoassays for the quantitative measurement of calcitonin in human serum.
The ADVIA Centaur System and Roche Elecsys/Cobas® share similar detection methods both utilizing chemiluminescent microparticle immunoassay (CMIA) technology. Both assays also demonstrated substantial equivalence as described in the table below:

**Comparison of the subject device with the predicate device:**

| **Similarities** | | |
|---|---|---|
| **Parameter** | **New submission device ADVIA Centaur® CALCT** | **Submission device Elecsys/Cobas® CALCT** |
| **Intended use** | The ADVIA Centaur® Calcitonin (CALCT) assay is for in vitro diagnostic use in the quantitative measurement of calcitonin in human serum using the ADVIA Centaur XP system. Calcitonin measurement is used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism. | The Calcitonin immunoassay is intended for the in vitro quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings. |
| **Assay Technology** | Automated. Chemiluminescent Microparticle Immunoassay (CMIA) | Automated. Chemiluminescent Microparticle Immunoassay (CMIA) |
| **Standardization** | WHO 2nd IRP 89/620 | WHO 2nd IRP 89/620 |
| **Specimen type** | Human serum and serum separator tubes. | Human serum and serum separator tubes. |
| **Test principle** | Sandwich principle | Sandwich principle |
| **Reagent storage** | Intended Storage of 2-8 $^{O}$C | Intended Storage of 2-8 $^{O}$C |
| **Reagent stability** | unopened: stabile until expiry | unopened: stabile until expiry |
| **Calibration** | 2-point calibration & master curve (via reagent barcode) | 2-point calibration & master curve (via reagent barcode) |
| **Measuring interval** | 1.75 - 2000.00 pg/mL | 1.0-2000 pg/mL |
| **Linear range** | 1.75 –2000.00 pg/mL | LOQ –2000.00 pg/mL |
| **Dilution Capabilities** | 1:100 (auto only) | 1:100 (auto and manual) |
| **On-system reagent stability** | 28 days | 28 days |

| **Differences** | | |
|---|---|---|
| **Parameter** | **New submission device<br>ADVIA Centaur® CALCT** | **Submission device<br>Elecsys/Cobas® CALCT** |
| **Calibration** | 14 –days lot-specific | 7 –days lot-specific |
| **Expected Values in Asymptomatic Population** | Reference ranges for 240 apparently healthy subjects, males (n = 120) and females (n = 120).<br>The age range was 22–79 years.<br>Reference intervals were determined using the 97.5th percentiles as upper limit of normal.<br>Males: ≤ 13.38 pg/mL (≤ 3.91 pmol/L)<br>Females: ≤ 9.53 pg/mL (≤ 2.79 pmol/L) | Reference ranges for apparently health males (n=184) and apparently healthy females (n=180) were determined using the 97.5th percentiles as upper limit of normal.<br>Females: 7.63 pg/mL (95% CI 6.1-12.7 pg/mL)<br>Males: 14.3 pg/mL (95%CI 10.4-18.0 pg/mL) |
| **High Dose hook** | no high-dose hook effect at concentrations up to 1,200,000 pg/mL | no high-dose hook effect at concentrations up to 1 µg/mL |
| **Detection Capability** | Limit of Quantitation = 1.75 pg/mL | Limit of Quantitation = 1 pg/mL |
| **Specimen Stability** | Separated specimens are stable for up to: 4 hours at room temperature<br>1 day at 2-8 ºC. 3 weeks at -20ºC<br>11 weeks at -70ºC<br>Specimens may undergo 1 freeze-thaw cycle. | Specimens may be stored for up to: 4 hours at 20-25 ºC<br>1 day at 2-8 ºC.<br>3 months at -20ºC<br>Specimens may undergo 1 freeze-thaw cycle. |
| **Specimen type** | Human serum. | Human Serum and plasma (K2-EDTA, K3-EDTA, Lithium Heparin with and without gel) |

**Summary of Non-Clinical Performance:**

The ADVIA Centaur CALCT assay demonstrated substantially equivalent performance to the Roche Elecsys/Cobas® calcitonin assay. A summary of the non-clinical performance data included in this 510(k) submission has been presented.

**Linearity**

Linearity was evaluated according to the CLSI protocol EP06-A.
Two samples containing high levels of calcitonin were mixed with analyte-free human serum. The resulting sample mixtures were assayed for calcitonin. The ADVIA Centaur CALCT assay is linear from 1.75–2000.00 pg/mL
(0.51-585.20 pmol/L).

**Dilution Recovery**

Fourteen samples containing high levels of calcitonin (2002.73 - 206737.95 pg/mL (586.00 - 60491.52 pmol/L)) were diluted 1:100 (1 part sample plus 99 parts diluent) with ADVIA Centaur Multi-Diluent 13 and assayed for recovery correcting the diluted sample by the dilution factor.
In a representative study the observed percent recovery for individual samples ranged from 82.8% to 117.4%.

**Measuring Interval**

The ADVIA Centaur CALCT assay measures calcitonin concentrations from 1.75-2000.00 pg/mL (0.51–585.20 pmol/L).

**Detection Capability**

The limit of blank (LoB), limit of detection (LoD), and the limit of quantitation (LoQ) were determined as described in CLSI Document EP17-A2.28 The ADVIA Centaur CALCT assay is designed to have an LoQ of < 2.00 pg/mL
(< 0.59 pmol/L).
The LoB is defined as the highest measurement result that is likely to be observed for a blank sample. The ADVIA Centaur CALCT assay has an LoB of
1.29 pg/mL (0.38 pmol/L).
The LoD is defined as the lowest concentration of calcitonin that can be detected with 95% probability. The ADVIA Centaur CALCT assay has an LoD of
1.65 pg/mL (0.48 pmol/L) based on 125 determinations using 6 low level samples, and an LoB of 1.29 pg/mL (0.38 pmol/L).

The LoQ is defined as the lowest concentration of calcitonin that can be detected at a total error of 20%. The ADVIA Centaur CALCT assay has an LoQ of 1.75 pg/mL (0.51 pmol/L). Report results below the LoQ as < 1.75 pg/mL (< 0.51 pmol/L).

**High Dose Hook**

Patient samples with high calcitonin levels can cause a paradoxical decrease in the Relative Light Units (RLUs) (high-dose hook effect). In the ADVIA Centaur CALCT assay, patient samples with calcitonin levels as high as 1,200,000 pg/mL (351,120 pmol/L) will assay greater than 2000.00 pg/mL (585.20 pmol/L**).**

**Cross-reactivity**

Cross-reactivity was tested in the presence of calcitonin at concentrations in the range of 7.57–11.65 pg/mL (2.21–3.41 pmol/L) and less than 2.01 pg/mL (0.59 pmol/L) of calcitonin according to CLSI EP07-A2.
The ADVIA Centaur CALCT assay shows minimal cross-reactivity with the following cross-reactants tested;

| Cross-reactant | Concentration | % cross reactivity |
|---|---|---|
| Adrenocorticotropic hormone (ACTH) | 200 ng/mL | ND[a] |
| Calcitonin gene-related peptide | 2000 ng/mL | ND |
| Chicken calcitonin | 1000 ng/mL | ND |
| C-peptide | 80,000 ng/mL | ND |
| Elcatonin | 200,000 ng/mL | ND |
| Gastrin | 4000 ng/mL | ND |
| Insulin | 67,000 ng/mL | ND |
| Katacalcin | 80,000 ng/mL | ND |

| Cross-reactant | Concentration | % cross reactivity |
|---|---|---|
| Pentagastrin | 7.5 ng/mL | -0.03% |
| Porcine calcitonin | 1000 ng/mL | ND |
| Procalcitonin | 100 ng/mL | ND |
| Prolactin"' | 2000 ng/mL | ND |
| PTH (1-84) | 300 ng/mL | ND |
| Salmon calcitonin | 200 ng/mL | ND |
| TSH | 2000 µIU/mL | ND |

[a] ND = not detected

**Interference**

Potential interference in the ADVIA Centaur CALCT assay from hemoglobin, bilirubin, and lipemia, is designed to be < 10% at calcitonin concentrations of 8.00–12.00 pg/mL (2.34–3.51 pmol/L) and 350.00-450.00 pg/mL (102.41 -131.67 pmol/L). Interfering substances at the levels indicated in the table below were tested as described in CLSI Document EP07-A227 using the ADVIA Centaur CALCT assay.

| Serum specimens that are... | Have an insignificant effect on the assay up to... |
|---|---|
| Hemolyzed | 500 mg/dL (0.31 mmol/L) of hemoglobin |
| Icteric | 60 mg/dL (1026 µmol/L) of unconjugated bilirubin |
| Icteric | 40 mg/dL (475 µmol/L) of conjugated bilirubin |
| Lipemic | 3000 mg/dL (34.0 mmol/L) of lipemia (Intralipid) |

Two levels of calcitonin were tested with each of the following substances at the levels indicated, and caused no significant interference in the ADVIA Centaur CALCT assay at calcitonin concentrations of 5.33–12.94 pg/mL (1.56–3.79 pmol/L) and 196.79–520.50 pg/mL (57.58–152.30 pmol/L).

| Substances | Concentrations |
|---|---|
| Acetaminophen | 1000 mg/L |
| Albumin (human) | 6 g/dL (60 g/L) |
| Amiodarone | 6.08 µg/mL (8.92 µmol/L) |
| Ascorbic Acid | 300 mg/L |
| Carbimazol | 30 µg/mL |
| Cholesterol | 500 mg/dL (12.95 mmol/L) |
| Cobozantinib | 0.6 µg/mL |
| Fluocortolon | 270 ng/mL |
| Human gamma globulins | 6 g/dL (60 g/L) |
| Hydrocortisone | 984 ng/mL |
| Ibuprofen | 500 mg/L |
| Iodide | 0.2 µg/mL |
| Octreotid acetate (sandostatin) | 5.2 ng/mL |
| Perchlorate | 200 µg/mL |
| Prednisolone | 3 µg/mL (8.31 µmol/L) |
| Propranolol | 2 µg/mL (7.71 µmol/L) |
| Propylthiouracil | 7.2 µg/mL |
| Rheumatoid factor | 200 IU/mL |
| Silwet L720 | 0.2 mg/dL |
| Sodium Heparin | 300 U/dL |
| Thiamazol | 80 µg/mL |
| Total protein | 12 g/dL (120 g/L) |
| Vandetanib | 1 µg/mL |

Biotin was added to serum samples containing different levels of calcitonin. These samples were tested against appropriate controls and the observed bias is presented in the table below:

| Substance | Substance Test Concentration (ng/mL) | Analyte Concentration (pg/mL) | Analyte Concetration (pmol/L) | Bias (%) |
|---|---|---|---|---|
| biotin, serum | 500,000 | 268.92 | 78.69 | 3.7 |
| biotin, serum | 1500 | 8.23 | 2.41 | -19.6 |
| | 750 | 8.66 | 2.53 | -15.4 |
| | 375 | 8.91 | 2.61 | -13 |
| | 187.5 | 8.36 | 2.45 | -18.3 |
| | 93.75 | 8.45 | 2.47 | -17.4 |
| | 46.875 | 9.01 | 2.64 | -12 |
| | 23.439 | 9.30 | 2.72 | -9.2 |

**Precision**

Precision was evaluated according to the CLSI protocol EP05-A3. The assay precision was designed to have a Within-Laboratory %CV of < 9%.

Five pooled serum samples were prepared with calcitonin concentrations spanning the measuring interval. Samples were tested in replicates of 2, in 2 runs per day, over 20 days, yielding 80 observations per sample.

Two ADVIA Centaur XP systems and 3 reagent lots were used. Representative data from the study is shown in the following table:

| | | Mean | | Repeatability (Within-Run) | | | Within-Lab (Total) | | |
|---|---|---|---|---|---|---|---|---|---|
| Specimen Type | N | (pg/mL) | (pmol/L) | SD (pg/mL) | SD (pmol/L) | CV (%) | SD (pg/mL) | SD (pmol/L) | CV (%) |
| Sample 1 | 80 | 5.51 | 1.61 | 0.25 | 0.07 | 4.5 | 0.47 | 0.14 | 8.5 |
| Sample 2 | 80 | 10.60 | 3.10 | 0.38 | 0.11 | 3.6 | 0.61 | 0.18 | 5.8 |
| Sample 3 | 80 | 36.97 | 10.82 | 1.33 | 0.39 | 3.6 | 1.57 | 0.46 | 4.3 |
| Sample 4 | 80 | 388.46 | 113.66 | 10.60 | 3.10 | 2.7 | 14.91 | 4.36 | 3.8 |
| Sample 5 | 80 | 1615.59 | 472.72 | 34.56 | 10.11 | 2.1 | 53.09 | 15.53 | 3.3 |

**Specimen Collection Comparison**

The ADVIA Centaur CALCT assay was evaluated using different human serum matrices. The assay is designed to have a correlation coefficient (r) > 0.95, a slope of 0.90–1.10, and an intercept ± 2.00 pg/mL (± 0.59 pmol/L) for alternate tube types (y) versus human serum (x). A specimen collection study was performed with serum calcitonin values ranging from approximately 2.50-2000.00 pg/mL (0.73–585.20 pmol/L). Passing-Bablok regression and a Pearson coefficient analysis were performed and no significant difference between tube types was observed. The following results were obtained:

| | | | Intercept | | |
|---|---|---|---|---|---|
| Human serum (x) vs | n | Slope | (pg/mL) | (pmol/L) | r |
| Serum Separator Tube (y) | 60 | 0.99 | 0.36 | 0.09 | 0.99 |

**Summary of Clinical Performance:**

The ADVIA Centaur anti-CCP IgG assay demonstrated substantially equivalent performance to the predicate as indicated by reference intervals (expected values) and a method comparison.

**Method Comparison**

The ADVIA Centaur CALCT assay is designed to have a correlation coefficient (r) > 0.95 compared to a comparable method.
A total of 97 human serum samples with calcitonin concentrations in the range of 1.01–1813.00 pg/mL (0.30–530.48 pmol/L) were tested over 4 discrete reagent lots. The relationship of the ADVIA Centaur CALCT assay (y) and a comparable method (x) is described using Passing-Bablok regression and a Pearson coefficient using the ADVIA Centaur XP system.

Representative data from the study is shown below:
ADVIA Centaur CALCT (y) = 0.97 (x) + 1.09 pg/mL (intercept), r = 0.98. ADVIA Centaur CALCT (y) = 0.97 (x) + 0.32 pmol/L (intercept), r = 0.98.

The correlation of the assay may vary depending on the study design, comparable method, and sample population according to EP09-A3. Assay results obtained at individual laboratories may vary from the data presented.

**Expected Values**

The ADVIA Centaur CALCT assay results were obtained on 240 apparently healthy subjects, males (n = 120) and females (n = 120). The age range was 22–79 years. Reference intervals were determined using the 97.5th percentiles as upper limit of normal according to EP28-A3c.

- Males: ≤ 13.38 pg/mL (≤ 3.91 pmol/L)
- Females: ≤ 9.53 pg/mL (≤ 2.79 pmol/L)

As with all in vitro diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results. Consider these values as guidelines only.

**Stability**

ADVIA Centaur CALCT Reagents are stable at 2–8°C until the expiration date on the product.
ADVIA Centaur CALCT Calibrators are stable at 2–8°C until the expiration date on the product.

- On-System Stability

The ADVIA Centaur CALCT assay reagents are stable unopened until the expiration date on the product or onboard the system for 28 days.
The ADVIA Centaur CALCT calibrators are stable unopened until the expiration date on the product or onboard the system for 4 hours.

**Standardization**

The ADVIA Centaur CALCT assay is traceable to the World Health Organization (WHO) 2nd International Reference Preparation for Calcitonin (Human); NIBSC code: 89/620. Assigned values for calibrators are traceable to this standard.

**Conclusion:**

**Based on the performance characteristics the ADVIA Centaur CALCT assay is substantially equivalent to the predicate device.**