October 8, 2025

Roche Diagnostics
Stephan Knierer
Regulatory Affairs Manager
9115 Hague Road
PO Box 50416
Indianapolis, Indiana 46250

Re: K252163
Trade/Device Name: Elecsys Phospho-Tau (181P) Plasma
Regulation Number: 21 CFR 866.5840
Regulation Name: Alzheimer's Disease Pathology Assessment Test
Regulatory Class: Class II
Product Code: SET
Dated: July 10, 2025
Received: July 10, 2025

Dear Stephan Knierer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252163

Device Name
Elecsys Phospho-Tau (181P) Plasma

Indications for Use *(Describe)*
Elecsys Phospho-Tau (181P) Plasma is an in vitro electrochemiluminescence immunoassay (ECLIA) intended for the measurement of the phosphorylated Tau 181 protein in human plasma on cobas e immunoassay analyzers.

The Elecsys Phospho-Tau (181P) Plasma assay result is intended to be used as an aid in the initial assessment for Alzheimer's disease and other causes of cognitive decline in adult patients aged 55 years and older, presenting with signs, symptoms, or complaints of cognitive decline. The result should be interpreted in conjunction with other clinical information.

A negative test result is consistent with a negative amyloid positron emission tomography (PET) scan result and reduced likelihood that a patient's cognitive impairment is due to amyloid pathology. These patients should be investigated for other causes of cognitive decline.

A positive test result may not be consistent with a positive amyloid PET scan result. Patients with an initial positive result should be further investigated to determine whether the amyloid pathology can be a cause of cognitive impairment.

Limitations of use
The Elecsys Phospho-Tau (181P) Plasma assay is not recommended for patients with signs, symptoms, or complaints of cognitive decline, who are already referred to the specialist.

The performance of Elecsys Phospho-Tau (181P) Plasma has not been established for:
- Predicting development of dementia or other neurologic conditions.
- Monitoring responses to therapies.

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.

510(k) Summary

21 CFR 807.92(a)(1)	
Date this summary was prepared	7/10/2025
Submitter's Name	Roche Diagnostics
Submitter's Address	9115 Hague Rd., Indianapolis, IN 46250 United States
Submitter's phone and email	stephan.knierer@roche.com
Contact person	Stephan Knierer

21 CFR 807.92(a)(2)	
Name of the Device (trade or proprietary as applicable) (and model numbers)	Elecsys Phospho-Tau (181P) Plasma (09697870190)
Common name	Elecsys Phospho-Tau (181P) Plasma
Classification name	Alzheimer's disease pathology assessment test
Regulation Number	866.5840
Product Code	SET

21 CFR 807.92(a)(3)	
Predicate Device	Elecsys β-Amyloid (1-42) CSF II, Elecsys Phospho-Tau (181P) CSF
Submission where de novo was granted	K221842
Product Code	QSE

21 CFR 807.92(a)(4)
Device Description Summary
In vitro electrochemiluminescence immunoassay (ECLIA) intended for the measurement of the phosphorylated Tau 181 protein (pTau181p) in human plasma. Elecsys Phospho-Tau (181P) Plasma utilizes a sandwich test principle and has a total duration time of 18 minutes. ▪ 1st incubation: 30 µL of sample, biotinylated monoclonal antibody specific for phosphorylation at threonine 181, and a monoclonal tau-specific antibody labeled with a ruthenium complex[a)] 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 II 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 cobas link.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy))

21 CFR 807.92(a)(5)
Intended use/Indications for Use
Elecsys Phospho-Tau (181P) Plasma is an in vitro electrochemiluminescence immunoassay (ECLIA) intended for the measurement of the phosphorylated Tau 181 protein in human plasma on cobas e immunoassay analyzers. The Elecsys Phospho-Tau (181P) Plasma assay result is intended to be used as an aid in the initial assessment for Alzheimer's disease and other causes of cognitive decline in adult patients aged 55 years and older, presenting with signs, symptoms, or complaints of cognitive decline. The result should be interpreted in conjunction with other clinical information. A negative test result is consistent with a negative amyloid positron emission tomography (PET) scan result and reduced likelihood that a patient's cognitive impairment is due to amyloid pathology. These patients should be investigated for other causes of cognitive decline. A positive test result may not be consistent with a positive amyloid PET scan result. Patients with an initial positive result should be further investigated to determine whether the amyloid pathology can be a cause of cognitive impairment. Limitations of use The Elecsys Phospho-Tau (181P) Plasma assay is not recommended for patients with signs, symptoms, or complaints of cognitive decline, who are already referred to the specialist. The performance of Elecsys Phospho-Tau (181P) Plasma has not been established for: ▪ Predicting development of dementia or other neurologic conditions. ▪ Monitoring responses to therapies.

21 CFR 807.92(a)(5)
Indications for Use Comparison
Elecsys Phospho-Tau (181P) Plasma is substantially equivalent to predicate device (K221842) in analytical and clinical performance. Both test systems measure a phosphorylated Tau biomarker. The candidate device uses plasma samples, whereas the predicate device uses cerebrospinal fluid samples. Both the candidate and predicate device use a single predefined cutoff value for classifying amyloid PET status as positive or negative.

21 CFR 807.92(a)(6)
Technological Comparison
The Roche Elecsys Phospho-Tau (181P) Plasma is substantially equivalent to the predicate device Elecsys Phospho-Tau (181P) CSF. Both products measure the respective analytes in a very similar fashion utilizing monoclonal antibodies which bind with the analyte and are both measured using chemoluminescence technology.

21 CFR 807.92(b)
Non-Clinical Tests Summary
Precision/Reproducibility: Repeatability and Intermediate Precision were conducted according to CLSI guidance EP05-A3 using one **cobas e** 801 analyzer and one reagent lot. Nine human K2-EDTA plasma samples spanning the measuring range were tested in two replicates per run, two runs separated by two hours per day for 21 days at a single site. Lot-to-lot Precision was conducted according to CLSI guidance EP05-A3 using one **cobas e** 801 analyzer and three reagent lots. Eight human K2-EDTA plasma samples spanning the measuring range were tested in three replicates per run, two runs separated by two hours per day for five days at a single site. Site-to-site Reproducibility was conducted according to CLSI guidance EP05-A3 at three sites with one **cobas e** 801 analyzer at each site. Eight human K2-EDTA plasma samples spanning the measuring range were tested in three replicates per run, two runs separated by two hours per day for five days. Results for all plasma samples and the two control (PC = PreciControl, PreciControl Phospho-Tau (181P) Plasma) tested in the precision and reproducibility studies met the predetermined acceptance criteria.
Limit of Blank (LoB): The limit of Blank was determined according to CLSI EP17-A2. Experimental design included three reagent lots evaluated on one **cobas e** 801 analyzer, six runs over three days with two replicates per run. Tau depleted plasma samples were used as the blank samples. The LoB claim in the labeling will be set to 0.250 pg/mL.
Limit of Detection (LoD): The limit of Detection was determined according to CLSI EP17-A2. Five human K2-EDTA plasma samples with low-analyte concentrations (i.e., > LoB) were measured with three lots in duplicate determination in six runs, distributed over three days, on one **cobas e** 801 analyzer. The LoD claim in the labeling was set to 0.300 pg/mL.
Limit of Quantitation (LoQ): The limit of Quantitation was determined according to CLSI EP17-A2. Seven human K2-EDTA plasma samples with analyte concentrations close to the specified LoQ were measured as 5 replicates in one run over 5 days. All lots met the predetermined acceptance criterion and the LoQ claim in the labeling was set to 0.300 pg/mL.
Linearity: Linearity was performed according to CLSI EP06-Ed2. Linearity was assessed on the **cobas e** 801 analyzer utilizing dilutions of three high native K2-EDTA plasma samples spiked with Tau(172-205)[pThr181] and a native sample that covers at least 50% of the measuring range Each sample dilution was measured in 4-fold determination within one run using one reagent lot. For each sample, the mean value of the measured values, predicted value and the deviation from linearity were calculated. Percent deviations from linearity (%DL) were calculated as differences between the observed values and the predicted values divided by the predicted values. The %DLs were within ± 10% for each dilution level in all four sample panels. The assay is linear over the measuring range of 0.300 pg/mL to 10 pg/mL.
High Dose Hook Effect:

To determine the hook concentration, two high concentration K2-EDTA plasma samples spiked with Tau(172-205)[pThr181)amid were used to prepare dilution series using analyte-depleted human K2-EDTA plasma. Each sample level was measured in three replicates within one run on a **cobas e** 801 analyzer and the measured counts were plotted against the expected sample concentrations. The data supports the claim that there is no hook effect up to 150 pg/mL.

Human Anti-Mouse Antibodies (HAMA):

The effect on quantitation of analyte in the presence of human anti-mouse antibodies was determined on the **cobas e** 801 analyzer. HAMA interference was assessed in two K2-EDTA plasma sample pools (low and slightly above the cut-off). One aliquot of each sample was spiked with the interfering substance (HAMA pool) at 1200 µg/mL (test sample) and another aliquot was spiked with the same volume of the base pool (control sample). Both pools were tested in the same run in five-fold determination. % interference was calculated by comparing measurements of the test and control samples. The result fulfilled the specification for HAMA interference.

Endogenous Interferences:

The effect on the quantitation of Elecsys Phospho-Tau (181P) Plasma in the presence of nine interfering substances (Hemoglobin, Bilirubin, Intralipid, Biotin, Rheumatoid Factor, Human Serum Albumin, IgG, IgM, IgA) was determined on the **cobas e** 801 analyzer. A total of four K2-EDTA plasma samples pools (low, medium, high and slightly above or below the cutoff) were prepared and tested in five-fold determination with one lot of reagents. For each interfering substance, one aliquot of each plasma sample was spiked with the potential interferent (test sample), another aliquot was spiked with the same volume of solvent used to create the interfering substances panel (control sample). % interference was calculated by comparing measurements of the test and control samples. All compounds exhibited no significant interference and met the acceptance criteria.

Exogenous (drugs) Interferences:

The effect on quantitation of the pTau181p analyte in the presence of exogenous interfering substances using the Elecsys Phospho-Tau (181P) Plasma was determined on the **cobas e** 801 analyzer. Seventeen common and twenty-six special pharmaceuticals were tested by spiking into three K2-EDTA human plasma sample pools (one low, one slightly above and one slightly below the cut-off). All plasma sample pools were divided into two aliquots. One was spiked with the potential interferent (test sample) and the other without interferent was spiked with the respective amount of solvent only (control sample). % interference was calculated by comparing measurements of the test and control samples. All compounds exhibited no significant interference and met the acceptance criteria.

Cross Reactivity / Analytical Specificity:

Cross-reactivity to reactivity to the non-phosphorylated Tau protein and pTau175 was assessed in two plasma sample pools within 20% above or below the cutoff. Each pool was divided into two aliquots, one that was spiked with 60 pg/mL non-phosphorylated Tau or pTau175 as putative cross reactant and one aliquot that served as dilution pool. Each level was tested in 5-fold measurements. The mean value was used to compare the expected value with the measured value. All values are within specification.

Lot Calibration Stability:

A set of thirteen K2-EDTA plasma samples covering the measuring range was generated for lot calibration stability testing on a **cobas e** 801 analyzer. A fresh reagent **cobas e** pack was

placed on the analyzer and calibrated. Reference values for the samples tested were determined in two runs and in duplicates at day 0. After 36, 84 and 91 days, a fresh kit (stored at 2-8°C) from the same lot was tested with the same samples, using the calibration established on day 0. Samples were tested in duplicates. Results of the samples at 91 days (13 weeks) were compared at the results of the samples at day 0, T0, using a Passing-Bablok regression analysis: slope was 0.971 with 95%CI: (0.956; 1.001), intercept was 0.0022 with 95%CI: (-0.0403; 0.0292), and %bias at the cutoff of 0.722 was -2.6%. The results of the study support the lot calibration stability claim of 84 days (12 weeks) when using a new Elecsys Phospho-Tau (181P) Plasma reagent kit of the same lot.

On-Board Calibration Stability:

A set of thirteen K2-EDTA plasma samples covering the measuring range was generated for onboard calibration stability testing. A fresh reagent cobas e pack was placed on the analyzer and calibrated. Reference values for the samples tested were determined in two runs and in duplicates at day 0. The same samples were tested in duplicates after 8, 15, 22, 28 and 29 days with the same reagents kept at 10°C +/- 2°C (on-board conditions) using the calibration established on day 0. The mean recovery compared to the mean reference value was determined for all plasma samples using the calibration curve established on day 0. All samples were within specification. The results support the on-board calibration stability claim of 28 days when using the same reagent kit kept in on-board condition.

Reagent On-Board Stability:

Reagent on-board stability for the Elecsys Phospho-Tau (181P) Plasma assay was tested on one **cobas e** 801 analyzer. A set of thirteen K2-EDTA plasma samples covering the measuring range was generated for reagent on-board stability testing. A freshly opened reagent cobas e pack was placed on the analyzer and calibrated. Reference values for the samples at time point t=0 were measured in two independent runs and with double determination. After 4, 8, 12, 16 and 17 weeks on the **cobas e** 801 analyzer (reagent kit kept at 10°C (± 2°C)), frozen aliquots of the same samples were measured again in duplicate with the stressed kit. The mean recovery compared to the mean reference value (time point 0) was determined for all samples All samples were within specification. The Elecsys Phospho-Tau (181P) Plasma reagent kits can be stored on-board of the analyzers for up to 16 weeks.

Reagent Shelf-life Stability:

Reagent shelf-life stability of the Elecsys Phospho-Tau (181P) Plasma **cobas e** pack was determined on one **cobas e** 801 analyzer using three reagent lots. A set of eight plasma samples covering the measuring range of the Elecsys Phospho-Tau (181P) Plasma assay was generated from native human plasma. To determine a robust reference value at time point t=0, the samples were measured in two independent runs and with double determination on a **cobas e** 801 analyzer. The median value from each sample at t=0 was calculated and set as a reference value. For the subsequent time points a new calibration is established and the samples are determined in one run in duplicates. The kits are continuously stored at 2-8 °C and aliquots of the above-mentioned samples are deep-frozen until the next measurement point. At each timepoint, absolute and relative recovery of the test samples with respect to the initial measurement at t=0 is evaluated. All samples are within specification.

Matrix Comparison:

Sample matrix equivalence was evaluated in accordance with the CLSI guideline EP35, 1st ed. for samples collected with five different blood collection tube types: K2-EDTA, K3- EDTA and K2-EDTA plasma gel separating tubes (PST). Fifty-six sample pairs per tube type with

pTau181 concentrations that span across the measuring range were tested in singleton with one reagent lot of Elecsys Phospho-Tau (181P) Plasma on a **cobas e** 801 analyzer. Passing-Bablok regression analysis was performed using pTau181 concentrations measured in samples collected with the primary tube (K2-EDTA without separating gel) compared to those in samples collected with each of the other tube types tested. Results were within specifications.

21 CFR 807.92(b)

Reference Range

A reference interval study was performed in accordance with the CLSI guideline EP28-A3c. The reference range for Elecsys Phospho-Tau (181P) Plasma was established from 174 cognitively normal individuals aged 55–80 years (mean: 65.1), including 95 males and 79 females (139 White, 17 Black or African American, 7 Asian, 10 other and 1 not reported). All subjects had a QDRS score of zero. pTau181p levels were measured in K2-EDTA samples using the **cobas e** 801 analyzer. The pTau181p median and 95% reference interval (2.5th; 97.5th percentile) were 0.658 pg/mL and 0.323 - 1.91 pg/mL, respectively. In this group, 61% were below and 39 % above the Elecsys Phospho-Tau (181P) Plasma assay cut-off for amyloid pathology, consistent with known rates of neuropathologic changes in cognitively normal individuals. No significant differences in pTau181p medians were found by gender or race (note: non-white groups had small sample sizes). pTau181p levels showed a slight increase with age, particularly in those over 70 years. The pTau181 median and 95% reference interval were 0.718 pg/mL and 0.358 - 3.43 pg/mL, respectively, in subjects (N=45) between 71–80 years old, and 0.631 pg/mL and 0.323 - 1.52 pg/mL, respectively, in subjects (N=129) between 55– 70 years old. Laboratories should verify these reference values for their own populations and establish local reference ranges if needed.
A significant correlation between age and pTau181p values in the reference range cohort (Spearman's rho = 0.306) was found.

	Cognitively normal					
	Race				**Sex**	
	White	**Black**	**Asian**	**Other**	**Male**	**Female**
N (%)	139 (79.9%)	17 (9.8%)	7 (4.0%)	10 (5.7%)	95 (54.6%)	79 (45.4%)
Mean (SD)	0.805 (0.491)	0.697 (0.308)	0.650 (0.229)	0.581 (0.285)	0.836 (0.533)	0.699 (0.341)
Median	0.667	0.594	0.668	0.484	0.701	0.594
Range	0.300 - 3.72	0.300 - 1.59	0.300 - 0.979	0.320 - 1.18	0.300 - 3.72	0.300 – 1.94
2.5th Percentile, 97.5th Percentile	0.358 - 1.94	N/A, N/A	N/A, N/A	N/A, N/A	0.342- 1.96	0.300- 1.91
N(%) >0.722	58 (41.7%)	6 (35.3%)	2 (28.6%)	2 (20.0%)	45 (47.4%)	23 (29.1%)

Results listed as not applicable (N/A) are due to an insufficient number of samples to properly calculate the value.
No race reported for one subject with mean pTau181 of 0.559 pg/mL.

	Cognitively normal		
	All	Age groups	
		55 to 70 years	71 to 80 years
N (%)	174 (100%)	129 (74.1%)	45 (25.9%)
Mean (SD)	0.774 (0.460)	0.703 (0.307)	0.976 (0.707)
Median	0.658	0.631	0.718
Range	0.300 - 3.72	0.300 - 1.94	0.300 - 3.72
2.5th Percentile, 97.5th Percentile	0.323 - 1.91	0.323 - 1.52	0.358 - 3.43
N(%) >0.722	68 (39.1%)	46 (35.7%)	22 (48.9%)

Clinical Tests Summary

A multicenter, prospective, non-interventional clinical study (Roche study RD006263) was conducted to evaluate the performance of Elecsys Phospho-Tau (181) Plasma.

The performance of Elecsys Phospho-Tau (181) Plasma was evaluated in 312 participants reflective of primary care, with respect to the following cutoff rule:

If pT181p is > 0.722 pg/mL, the test result is positive.
If pT181p is ≤ 0.722 pg/mL, the test result is negative.

This study population had an average age of 69.1 years (range 55–80 years) and presented with cognitive complaints or impairment, subjective or objective, of unknown cause, at 8 geographically diverse enrollment sites across the U.S. (n=6) and Europe (n=2). A total of 299 (95.8%) subjects were enrolled at U.S. sites and 13 (4.17%) at European sites.
The study population consisted of 40.7% (127/312) males with a mean age of 69.1 years (range 57-80 years with a median age of 69 years), and 59.3% females (185/312) with a mean age of 69.1 years (range 55-80 years with a median 69 years). In terms of race, 59.0% were white, 34.0% were black or African American, 1.6% were Asian, 0.321% were Middle Eastern, and 5.13% identified as other. Regarding ethnicity, 66.3% of participants were not Hispanic or Latino, 29.5% were Hispanic or Latino, and for 4.17% of the participants' information on the ethnicity was missing. The study population included participants with comorbidities frequently encountered in clinical practice such as cardiovascular disease (56.1%), diabetes (25.6%), depression (19.9%), kidney disease (2.24%), or history of cerebrovascular accident (3.53%) or cancer (12.5%), among others.
Cognitive assessments [QDRS, Mini-Mental State Examination (MMSE), Clinical Dementia Rating (CDR)], imaging [amyloid PET, Magnetic Resonance Imaging (MRI)] and questionnaires (including medical history, medication, quality of life, physical activity, and socio-demographics) were collected from the enrolled participants.
The study participants were then categorized into three diagnostic groups by their physician, based on cognitive test results and clinical assessments: 41.0% (128/312) subjective cognitive decline (SCD), 56.1% (175/312) mild cognitive impairment (MCI), and 0.962% (3/312) mild dementia. The diagnostic

category was unknown in 6 subjects (1.92%). The pre-dementia Alzheimer's disease diagnostic groups (SCD and MCI) represented 97.1% (303/312) of the study population.
The demographic and clinical characteristics of the patients in the three diagnostic groups are presented according to amyloid PET scan results in the table below:

	Diagnostic groups				**Visual Read amyloid PET**		
	SCD (N=128, 41.0%)	**MCI (N=175, 56.1%)**	**Mild dementia (N=3, 0.962%)**	**Missing (N=6, 1.92%)**	**Positive (N=41, 13.1%)**	**Negative (N=271, 86.9%)**	**All (N=312, 100%)**
Age [years]							
55 to 70	89 (69.5%)	81 (46.3%)	1 (33.3%)	4 (66.7%)	12 (29.3%)	163 (60.1%)	175 (56.1%)
71 to 80	39 (30.5%)	94 (53.7%)	2 (66.7%)	2 (33.3%)	29 (70.7%)	108 (39.9%)	137 (43.9%)
Mean (SD)	66.6 (5.87)	70.9 (6.27)	68.7 (9.29)	69.3 (6.98)	73.5 (5.09)	68.4 (6.38)	69.1 (6.46)
Median	66.0	72.0	73.0	68.0	75.0	68.0	69.0
Q1 ... Q3	62.3 ... 71.0	67.0 ... 76.0	58.0 ... 75.0	62.8 ... 76.8	69.5 ... 78.0	63.0 ... 74.0	64.0 ... 75.0
Min ... Max	55.0 ... 80.0	56.0 ... 80.0	58.0 ... 75.0	62.0 ... 79.0	59.0 ... 80.0	55.0 ... 80.0	55.0 ... 80.0
Sex							
Male	53 (41.4%)	73 (41.7%)	1 (33.3%)	0 (0%)	20 (48.8%)	107 (39.5%)	127 (40.7%)
Female	75 (58.6%)	102 (58.3%)	2 (66.7%)	6 (100%)	21 (51.2%)	164 (60.5%)	185 (59.3%)
Race							
White	74 (57.8%)	106 (60.6%)	1 (33.3%)	3 (50.0%)	37 (90.2%)	147 (54.2%)	184 (59.0%)
Asian	0 (0%)	5 (2.86%)	0 (0%)	0 (0%)	0 (0%)	5 (1.85%)	5 (1.60%)
Black or African American	51 (39.8%)	51 (29.1%)	2 (66.7%)	2 (33.3%)	4 (9.76%)	102 (37.6%)	106 (34.0%)
Middle Eastern	0 (0%)	1 (0.571%)	0 (0%)	0 (0%)	0 (0%)	1 (0.369%)	1 (0.321%)
Other[a)]	3 (2.34%)	12 (6.86%)	0 (0%)	1 (16.7%)	0 (0%)	16 (5.90%)	16 (5.13%)
Ethnicity							
Not Hispanic or Latino	69 (53.9%)	132 (75.4%)	2 (66.7%)	4 (66.7%)	32 (78.0%)	175 (64.6%)	207 (66.3%)
Hispanic or Latino	58 (45.3%)	31 (17.7%)	1 (33.3%)	2 (33.3%)	4 (9.76%)	88 (32.5%)	92 (29.5%)
Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missing	1 (0.781%)	12 (6.86%)	0 (0%)	0 (0%)	5 (12.2%)	8 (2.95%)	13 (4.17%)
BMI [kg/m^2]							

Mean (SD)	29.4 (5.61)	28.4 (5.21)	25.9 (4.83)	26.2 (3.68)	26.8 (4.11)	29.0 (5.49)	28.7 (5.37)
Median	28.5	27.5	24.8	27.1	25.8	28.3	27.8
Q1 ... Q3	25.7 ... 32.2	24.9 ... 31.2	21.8 ... 31.2	22.4 ... 29.2	23.9 ... 29.1	25.4 ... 31.8	25.2 ... 31.4
Min ... Max	16.5 ... 46.5	18.5 ... 48.8	21.8 ... 31.2	21.0 ... 30.6	20.7 ... 37.6	16.5 ... 48.8	16.5 ... 48.8
QDRS							
Mean (SD)	3.03 (1.59)	4.40 (2.64)	5.17 (1.04)	4.58 (1.28)	3.91 (2.43)	3.84 (2.33)	3.85 (2.34)
Median	2.50	4.00	5.50	4.50	3.00	3.00	3.00
Q1 ... Q3	2.00 ... 3.50	2.50 ... 6.00	4.00 ... 6.00	3.38 ... 5.75	2.50 ... 4.75	2.00 ... 5.00	2.00 ... 5.00
Min ... Max	0.500 ... 10.5	0.500 ... 11.5	4.00 ... 6.00	3.00 ... 6.50	1.00 ... 11.5	0.500 ... 11.0	0.500 ... 11.5
MMSE							
< 25	27 (21.1%)	48 (27.4%)	1 (33.3%)	2 (33.3%)	13 (31.7%)	65 (24.0%)	78 (25.0%)
25-27	77 (60.2%)	69 (39.4%)	2 (66.7%)	2 (33.3%)	15 (36.6%)	135 (49.8%)	150 (48.1%)
28-30	24 (18.8%)	58 (33.1%)	0 (0%)	2 (33.3%)	13 (31.7%)	71 (26.2%)	84 (26.9%)
Mean (SD)	25.9 (1.89)	26.2 (2.42)	24.3 (2.89)	26.5 (3.02)	26.1 (2.51)	26.0 (2.19)	26.1 (2.23)
Median	26.0	26.0	26.0	27.0	26.0	26.0	26.0
Q1 ... Q3	25.0 ... 27.0	24.0 ... 28.0	21.0 ... 26.0	23.5 ... 29.3	24.0 ... 29.0	25.0 ... 28.0	24.3 ... 28.0
Min ... Max	21.0 ... 30.0	21.0 ... 30.0	21.0 ... 26.0	22.0 ... 30.0	21.0 ... 30.0	21.0 ... 30.0	21.0 ... 30.0
CDR global							
0	15 (11.7%)	3 (1.71%)	0 (0%)	0 (0%)	3 (7.32%)	15 (5.54%)	18 (5.77%)
0.5	111 (86.7%)	165 (94.3%)	0 (0%)	0 (0%)	34 (82.9%)	242 (89.3%)	276 (88.5%)
1	2 (1.56%)	7 (4.00%)	3 (100%)	0 (0%)	2 (4.88%)	10 (3.69%)	12 (3.85%)
1.5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
2.5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	0 (0%)	6 (100%)	2 (4.88%)	4 (1.48%)	6 (1.92%)
CDR-SB							
Mean (SD)	1.86 (1.18)	2.18 (1.31)	5.00 (0.500)	NA (NA)	1.90 (1.58)	2.11 (1.25)	2.08 (1.30)
Median	2.00	2.00	5.00	NA	1.50	2.00	2.00
Q1 ... Q3	1.00 ... 2.50	1.00 ... 3.00	4.50 ... 5.50	NA ... NA	1.00 ... 2.50	1.00 ... 3.00	1.00 ... 3.00
Min ... Max	0 ... 7.50	0 ... 7.00	4.50 ... 5.50	Inf ... -Inf	0 ... 7.00	0 ... 7.50	0 ... 7.50

Missing (n, %)	13 (10.2%)	4 (2.29%)	0 (0%)	6 (100%)	2 (4.88%)	21 (7.75%)	23 (7.37%)
Education [years]							
Mean (SD)	13.4 (3.37)	15.2 (3.59)	15.0 (2.65)	17.0 (2.10)	16.2 (3.34)	14.2 (3.55)	14.5 (3.58)
Median	12.0	15.0	16.0	17.0	16.0	14.0	14.0
Q1 ... Q3	12.0 ... 16.0	12.0 ... 18.0	12.0 ... 17.0	15.5 ... 18.5	14.0 ... 18.0	12.0 ... 16.0	12.0 ... 16.0
Min ... Max	5.00 ... 24.0	7.00 ... 37.0	12.0 ... 17.0	14.0 ... 20.0	10.0 ... 25.0	5.00 ... 37.0	5.00 ... 37.0
ApoE4 status[b)]							
Carrier	43 (33.6%)	56 (32.0%)	1 (33.3%)	1 (16.7%)	23 (56.1%)	78 (28.8%)	101 (32.4%)
Non carrier	85 (66.4%)	119 (68.0%)	2 (66.7%)	5 (83.3%)	18 (43.9%)	193 (71.2%)	211 (67.6%)
Collection Site Location							
Europe	1 (0.781%)	12 (6.86%)	0 (0%)	0 (0%)	5 (12.2%)	8 (2.95%)	13 (4.17%)
U.S.	127 (99.2%)	163 (93.1%)	3 (100%)	6 (100%)	36 (87.8%)	263 (97.0%)	299 (95.8%)

BMI, body mass index; CDR, clinical dementia rating; CDR-SB, CDR sum of boxes: eGFR, estimated glomerular filtration rate; MCI, mild cognitive impairment; MMSE, Mini-Mental State Examination; PET, positron emission tomography, QDRS, Quick Dementia Rating System; SCD, subjective cognitive decline.

[a)] Including American Indian, Alaska Native and Native Hawaiian

[b)] Based on plasma ApoE4 levels (protein)

A total of 313 subjects underwent amyloid PET scans using FDA approved amyloid tracers (18F-Florbetapir, 18F-Florbetaben or 18F-Flutemetamol). The amyloid PET scans were randomly assigned, read and interpreted by three trained readers out of a pool of five, each reading independent of each other. Majority voting was used to classify each image as amyloid positive or negative, resulting in 41 (13.1%) positive, and 271 (86.9%) negative amyloid PET reads. The independent readers were blinded to all clinical information, including the patient's clinical status, diagnosis, and plasma and/or CSF biomarker measurements. Amyloid PET reads were conducted according to the approved instructions for use of the amyloid tracers. Positive concordance among readers occurred in 28 cases (8.95%) and negative concordance occurred in 260 cases (83.1%). Discordant positive readings occurred in 13 cases (4.15%) and discordant negative readings occurred in 11 cases (3.51%). There were no cases with one or two missing ratings, and only 1 case (0.319%) had three missing ratings. The total available amyloid PET scans were 312.

The Positive Percent Agreement (PPA) between readers was 81.6% on average (range: 53.8% - 100%), the Negative Percent Agreement (NPA) was 97.1% on average (range: 91.5% - 100%), and the Total Percent Agreement (TPA) was 94.9% on average (range: 92.3% - 96.6%).

The time difference between blood collection and PET imaging exhibited a mean of 52.2 days (SD = 34.8), a median of 39 days, and ranged from -15 to 179 days. Timing was consistent between PET positive (mean = 45.8 days; SD = 29.9; median = 35 days; range: 8 to 112 days) and PET negative (mean = 53.1 days; SD = 35.5; median = 39 days, range: -15 to 179 days) participants.

The agreement of Phospho-Tau (181) Plasma with visual read amyloid PET classification at the Phospho-Tau (181) Plasma cut-off of 0.722 pg/mL is summarized in the table below:

pT181p result	**Amyloid PET Visual read**		**Total**
	Positive	**Negative**	
Positive (pT181p > 0.722 pg/mL)	38	132	170
Negative (pT181p ≤ 0.722 pg/mL)	3	139	142
Total	41	271	312

PET, positron emission tomography.

The prevalence of amyloid positivity based on amyloid PET was 13.1% in the study population.
Elecsys Phospho-Tau (181) Plasma agreement rates percentages and likelihood ratios are summarized in the table below:

Study population	
N	312
Visual Read Amyloid PET Negative (% N) (95% CI)	 86.9% (82.7% - 90.2%)[a)]
PPA (n/N) (95% CI)	92.7% (38/41) (80.6% - 97.5%)[a)]
NPA (n/N) (95% CI)	51.3% (139/271) (45.4% - 57.2%)[a)]
TPA (n/N) (95% CI)	56.7% (177/312) (51.2% - 62.1%)[a)]
PPV (n/N) (95% CI)	22.4% (38/170) (19.5% - 25.0%)[b)]

NPV	97.9%
(n/N)	(139/142)
(95% CI)	(94.5% - 99.3%)[b)]
LR+	1.90
(95% CI)	(1.601-2.200)[c)]
LR-	0.143
(95% CI)	(0.049-0.382)[c)]
Rule-out rate	45.5%
(n/N)	(142/312)
(95% CI)	(40.1% - 51.1%)[a)]

LR, likelihood ratio; NPA, negative percent agreement; NPV, negative predictive value; PET, positron emission tomography; PPA, positive percent agreement; PPV, positive predictive value; TPA, total percent agreement.
[a)]95 % CI are calculated using a Wilson score method for binomial proportions.
[b)]95 % CI are calculated using 95 % CI for the corresponding likelihood ratio and prevalence
[c)]95 % CI are calculated using an asymptotic method for ratios of two independent binomial proportions

Of the 41 subjects with a positive PET scan, 3 (7.3%) had a false negative Phospho-Tau (181) PlasmapT181p result. The NPV was 97.9%. 45.5% (142/312) of all subjects received a negative Phospho-Tau (181) Plasma result.

The Elecsys Phospho-Tau (181) Plasma clinical performance stratified by clinical diagnosis is summarized in the table below:

N=306	**SCD**	**MCI**	**Mild dementia**
N	128	175	3
(% Total)	(41.8%)	(57.2%)	(0.980%)
Visual Read Amyloid PET Negative			
(% N)	95.3%	81.1%	100%
(95% CI)	(90.2% - 97.8%)[a)]	(74.7% - 86.2%)[a)]	(43.9% - 100%)[a)]
PPA	83.3%	97.0%	NaN%
(n/N)	(5/6)	(32/33)	(0/0)
(95% CI)	(43.7% - 97.0%)[a)]	(84.7% - 99.5%)[a)]	
NPA	54.9%	47.9%	66.7%
(n/N)	(67/122)	(68/142)	(2/3)
(95% CI)	(46.1% - 63.5%)[a)]	(39.8% - 56.1%)[a)]	(20.8% - 93.9%)[a)]

TPA	56.3%	57.1%	66.7%
(n/N)	(72/128)	(100/175)	(2/3)
(95% CI)	(47.6% - 64.5%)[a)]	(49.7% - 64.2%)[a)]	(20.8% - 93.9%)[a)]
PPV	8.33%	30.2%	0%
(n/N)	(5/60)	(32/106)	(0/1)
(95% CI)	(4.4% - 10.8%)[b)]	(26.5% - 34.0%)[b)]	(0% - 79.3%)[b)]
NPV	98.5%	98.6%	100%
(n/N)	(67/68)	(68/69)	(2/2)
(95% CI)	(95.1% - 99.7%)[b)]	(93.0% - 99.70%)[b)]	(34.2% - 100%)[b)]
LR+	1.85	1.86	NaN
(95% CI)	(0.94 - 2.47)[c)]	(1.55 - 2.20)[c)]	
LR-	0.303	0.0633	NaN
(95% CI)	(0.054 - 1.050)[c)]	(0.011 - 0.324)[c)]	
Rule-out rate	53.1%	39.4%	66.7%
(n/N)	(68/128)	(69/175)	(2/3)
(95% CI)	(44.5% - 61.6%)[a)]	(32.5% - 46.8%)[a)]	(20.8% - 93.9%)[a)]

LR, likelihood ratio; MCI, mild cognitive impairment; NPA, negative percent agreement; NPV, negative predictive value; PET, positron emission tomography; PPA, positive percent agreement; PPV, positive predictive value; SCD, subjective cognitive decline; TPA, total percent agreement.

[a)]95 % CI are calculated using a Wilson score method for binomial proportions.

[b)]95 % CI are calculated using 95 % CI for the corresponding likelihood ratio and prevalence

[c)]95 % CI are calculated using an asymptotic method for ratios of two independent binomial proportions

The Elecsys Phospho-Tau (181) Plasma clinical performance stratified by sex is summarized in the table below:

N=312	**Male**	**Female**
N	127	185
(% Total)	(40.7%)	(59.3%)
Visual Read Amyloid PET Negative		
(% N)	84.3%	88.6%
(95% CI)	(76.9% - 89.6%)[a)]	(83.3% - 92.5%)[a)]
PPA	90.0%	95.2%
(n/N)	(18/20)	(20/21)
(95% CI)	(69.9% - 97.2%)[a)]	(77.3% - 99.2%)[a)]
NPA	53.3%	50.0%
(n/N)	(57/107)	(82/164)
(95% CI)	(43.9% - 62.4%)[a)]	(42.4% - 57.6%)[a)]
TPA	59.1%	55.1%

(n/N)	(75/127)	(102/185)
(95% CI)	(50.4% - 67.2%)[a)]	(47.9% - 62.1%)[a)]
PPV	26.5%	19.6%
(n/N)	(18/68)	(20/102)
(95% CI)	(21.0% - 31.5%)[b)]	(16.1% - 22.6%)[b)]
NPV	96.6%	98.8%
(n/N)	(57/59)	(82/83)
(95% CI)	(90.3% - 99.0%)[b)]	(94.4% - 99.8%)[b)]
LR+	1.93	1.90
(95% CI)	(1.42 - 2.46)[c)]	(1.50 - 2.28)[c)]
LR-	0.188	0.0952
(95% CI)	(0.052 - 0.578)[c)]	(0.017 - 0.659)[c)]
Rule-out rate	46.5%	44.9%
(n/N)	(59/127)	(83/185)
(95% CI)	(38.0% - 55.1%)[a)]	(37.9% - 52.1%)[a)]

LR, likelihood ratio; NPA, negative percent agreement; NPV, negative predictive value; PET, positron emission tomography; PPA, positive percent agreement; PPV, positive predictive value; TPA, total percent agreement.
[a)]95 % CI are calculated using a Wilson score method for binomial proportions.
[b)]95 % CI are calculated using 95 % CI for the corresponding likelihood ratio and prevalence
[c)]95 % CI are calculated using an asymptotic method for ratios of two independent binomial proportions

The Elecsys Phospho-Tau (181) Plasma clinical performance stratified by age group is summarized in the table below:

N=312	**55 to 70 years**	**71 to 80 years**
N	175	137
(% Total)	(56.1%)	(43.9%)
Visual Read Amyloid PET Negative		
(% N)	93.1%	78.8%
(95% CI)	(88.4% - 96.0%)[a)]	(71.3% - 84.8%)[a)]
PPA	100%	89.7%
(n/N)	(12/12)	(26/29)
(95% CI)	(75.8% - 100%)[a)]	(73.6% - 96.4%)[a)]
NPA	63.8%	32.4%
(n/N)	(104/163)	(35/108)
(95% CI)	(56.2% - 70.8%)[a)]	(24.3% - 41.7%)[a)]
TPA	66.3%	44.5%
(n/N)	(116/175)	(61/137)

(95% CI)	(59.0% - 72.9%)[a)]	(36.5% - 52.9%)[a)]
PPV	16.9%	26.3%
(n/N)	(12/71)	(26/99)
(95% CI)	(13.0% - 20.1%)[b)]	(22.2% - 29.8%)[b)]
NPV	100%	92.1%
(n/N)	(104/104)	(35/38)
(95% CI)	(96.7% - 100%)[b)]	(81.3% - 97.2%)[b)]
LR+	2.76	1.33
(95% CI)	(2.03 - 3.43)[c)]	(1.06 - 1.58)[c)]
LR-	0	0.319
(95% CI)	(0.000 - 0.383)[c)]	(0.107 - 0.855)[c)]
Rule-out rate	59.4%	27.7%
(n/N)	(104/175)	(38/137)
(95% CI)	(52.0% - 66.4%)[a)]	(20.9% - 35.8%)[a)]

LR, likelihood ratio; NPA, negative percent agreement; NPV, negative predictive value; PET, positron emission tomography; PPA, positive percent agreement; PPV, positive predictive value; TPA, total percent agreement.
[a)]95 % CI are calculated using a Wilson score method for binomial proportions.
[b)]95 % CI are calculated using 95 % CI for the corresponding likelihood ratio and prevalence
[c)]95 % CI are calculated using an asymptotic method for ratios of two independent binomial proportions

The Elecsys Phospho-Tau (181) Plasma clinical performance stratified by race is summarized in the table below:

N=312	**White**	**Asian**	**Black or African American**	**Other**
N	184	5	106	17
(% Total)	(59.0%)	(1.60%)	(34.0%)	(5.45%)
Visual Read Amyloid PET Negative				
(% N)	79.9%	100%	96.2%	100%
(95% CI)	(73.5% - 85.0%)[a)]	(56.6% - 100%)[a)]	(90.7% - 98.5%)[a)]	(81.6% - 100%)[a)]
PPA	94.6%	NaN%	75.0%	NaN%
(n/N)	(35/37)	(0/0)	(3/4)	(0/0)
(95% CI)	(82.3% - 98.5%)[a)]		(30.1% - 95.4%)[a)]	
NPA	44.9%	40.0%	56.9%	76.5%
(n/N)	(66/147)	(2/5)	(58/102)	(13/17)
(95% CI)	(37.1% - 53.0%)[a)]	(11.8% - 76.9%)[a)]	(47.2% - 66.1%)[a)]	(52.7% - 90.4%)[a)]
TPA	54.9%	40.0%	57.5%	76.5%
(n/N)	(101/184)	(2/5)	(61/106)	(13/17)
(95% CI)	(47.7% - 61.9%)[a)]	(11.8% - 76.9%)[a)]	(48.0% - 66.5%)[a)]	(52.7% - 90.4%)[a)]

PPV	30.2%	0%	6.38%	0%
(n/N)	(35/116)	(0/3)	(3/47)	(0/4)
(95% CI)	(26.5% - 33.9%)[b)]	(0% - 56.1%)[b)]	(2.6% - 9.1%)[b)]	(0% - 49.0%)[b)]
NPV	97.1%	100%	98.3%	100%
(n/N)	(66/68)	(2/2)	(58/59)	(13/13)
(95% CI)	(90.8% - 99.2%)[b)]	(34.2% - 100%)[b)]	(95.3% - 99.7%)[b)]	(77.2% - 100%)[b)]
LR+	1.72	NaN	1.74	NaN
(95% CI)	(1.43 - 2.03)[c)]		(0.70 - 2.54)[c)]	
LR-	0.120	NaN	0.440	NaN
(95% CI)	(0.0329 - 0.4012)[c)]		(0.079 - 1.270)[c)]	
Rule-out rate	37.0%	40.0%	55.7%	76.5%
(n/N)	(68/184)	(2/5)	(59/106)	(13/17)
(95% CI)	(30.3% - 44.1%)[a)]	(11.8% - 76.9%)[a)]	(46.2% - 64.8%)[a)]	(52.7% - 90.4%)[a)]

LR, likelihood ratio, NPA, negative percent agreement; NPV, negative predictive value; PET, positron emission tomography; PPA, positive percent agreement; PPV, positive predictive value; TPA, total percent agreement.

[a)]95 % CI are calculated using a Wilson score method for binomial proportions.

[b)]95 % CI are calculated using 95 % CI for the corresponding likelihood ratio and prevalence

[c)]95 % CI are calculated using an asymptotic method for ratios of two independent binomial proportions

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Substantial Equivalence Summary

The Elecsys Phospho-Tau (181P) Plasma is substantially equivalent to the predicate device (K221842). Both test systems measure the phosphorylated pTau181 protein and are intended to aid in the assessment of adult patients aged 55 years and older, presenting with signs, symptoms, or complaints of cognitive decline, who are being evaluated for Alzheimer's disease and other causes of cognitive decline. Based on the clinical performance measures, PPA and NVP, the candidate device demonstrates substantially equivalent rule out performance compared to the predicate device.