Alinity i FSH-14

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BIENNIAL REVIEW:

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SUPERSEDES: Procedure titled _____

INTENDED USE

The Alinity i FSH assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of follicle stimulating hormone (FSH) in human serum and plasma on the Alinity i analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Human Follicle Stimulating Hormone (FSH, follitropin) is a glycoprotein of approximately 30 000 daltons which, like luteinizing hormone (LH, lutropin), human chorionic gonadotropin (hCG) and thyroid stimulating hormone (TSH, thyrotropin), consists of two

noncovalently associated subunits designated α and β.[1] The α subunit of FSH contains 92 amino acids and is very similar to the α subunits of LH, hCG, and TSH.[1] The β subunit of FSH is unique and confers its immunological and functional specificity.[1]

FSH and LH control growth and reproductive activities of the gonadal tissues.[2, 3] FSH promotes follicular development in the ovary and gametogenesis in the testis.[3, 4] The gonadotroph cells of the anterior pituitary secrete both FSH and LH in response to gonadotropin releasing hormone (LHRH or GnRH) from the medial basal hypothalamus.[5] Both FSH and LH are secreted in a pulsatile manner, with rapid fluctuations over the normal range.[3, 6, 7] The pulsatility of FSH is less pronounced than that of LH. Release of both FSH and LH from the pituitary is under negative feedback control by the gonads.[5]

FSH in mature females acts to stimulate development of the ovarian follicles. Circulating FSH levels vary throughout the menstrual cycle in response to estradiol and progesterone. A small, but significant increase in circulating FSH accompanies the mid-cycle LH surge. However, the physiological significance of this increase is unknown. Circulating levels of FSH decline in the luteal phase in response to estradiol and progesterone production by the developing corpus luteum.[2, 5]

At menopause, ovarian function is diminished with concomitant decrease in estradiol secretion. FSH and LH then increase significantly in response to diminished feedback inhibition of gonadotropin release.[8, 9] In males, FSH, LH, and testosterone regulate spermatogenesis by the Sertoli cells in the seminiferous tubules of the testes. FSH is less sensitive to feedback inhibition by testosterone than is LH and is thought to be regulated independently by the inhibitory peptide inhibin produced by the Sertoli cells.[10, 11] Because of the negative feedback mechanisms regulating gonadotropin release, elevated concentrations of LH and FSH are indicative of gonadal failure when accompanied by low concentrations of the gonadal steroids. In males, these observations suggest primary testicular failure or anorchia.[4] FSH may also be elevated in Klinefelter's syndrome (seminiferous tubule dysgenesis) or as a consequence of Sertoli cell failure.[4] In females, situations in which FSH is elevated and gonadal steroids are depressed include menopause, premature ovarian failure, and ovariectomy, while with polycystic ovarian syndrome the LH/FSH ratio may be increased.[7]

Abnormal FSH concentrations may also indicate dysfunction of the hypothalamic-pituitary axis. In sexually mature adults, FSH deficiency, together with low concentrations of LH and sex steroids, may indicate panhypopituitarism.[7] This can result either from a decrease in the release of GnRH or from a lack of response of the pituitary to GnRH. Determination of serum FSH, following administration of GnRH, may allow differentiation of these two conditions.[5, 7] The use of oral contraceptives usually results in reduction of gonadotropin levels due to negative feedback by these steroids.[5]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

This assay is an automated two-step immunoassay for the quantitative determination of FSH in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample and anti-β FSH coated paramagnetic microparticles are combined and incubated. The FSH present in the sample binds to the anti-β FSH coated microparticles. The mixture is

washed. Anti-α FSH acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of FSH in the sample and the RLUs detected by the system optics.

For additional information on system and assay technology**, refer to the Alinity ci-series Operations Manual, Section 3.**

REAGENTS

Kit Contents

Alinity i FSH Reagent Kit 07P49

NOTE: Some kit sizes are not available in all countries. Please contact your local distributor.

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	07P4920	07P4930
Tests per cartridge	100	600
Number of cartridges per kit	2	2
Tests per kit	200	1200
MICROPARTICLES	6.6 mL	32.1 mL
CONJUGATE	6.1 mL	31.6 mL
MICROPARTICLES Anti-β FSH (mouse, monoclonal) coated microparticles in MES buffer with protein (murine and caprine) stabilizers. Minimum concentration: 0.1% solids. Preservative: antimicrobial agents.		
CONJUGATE Anti-α FSH (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 45 ng/mL. Preservative: antimicrobial agents.		

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national,

and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[12, 13, 14, 15]

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or/and SDS folder.

For a detailed discussion of safety precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 8.**

Reagent Handling

Upon receipt, gently invert the unopened reagent kit by rotating it over and back for a full 180 degrees, 5 times with green label stripe facing up and then 5 times with green label stripe facing down. This ensures that liquid covers all sides of the bottles within the cartridges. During reagent shipment, microparticles can settle on the reagent septum.

- Place a check in the square on the reagent kit to indicate to others that the inversions have been completed.
- After mixing, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 7.**

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain upright, gently invert the cartridge 10 times and place in an upright position for 1 hour before use.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
			upright during storage, discard the cartridge. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- a control value is out of the specified range

Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10**.

INSTRUMENT PROCEDURE

The Alinity i FSH assay file must be installed on the Alinity i analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, **refer to the Alinity ci-series Operations Manual.**

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mIU/mL	1	IU/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Specimen Types	Collection Tubes
Serum	Serum Serum separator
Plasma	Lithium heparin Sodium heparin Potassium EDTA

Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by gently inverting prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by gently inverting.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/Plasma	2 to 8°C	7 days	If testing will be delayed more than 24 hours, remove serum or plasma from the clot, serum separator or red blood cells. If testing will be delayed more than 7 days, specimens should be stored frozen at -10°C or colder.
	-10°C or colder	12 months	Remove serum or plasma from the clot, red blood cells, or separator gel.[16]

Avoid multiple freeze/thaw cycles.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

07P49Alinity i FSH Reagent Kit

Materials Required but not Provided

- Alinity i FSH assay file
- 07P4901 Alinity i FSH Calibrators
- 07P4910 Alinity i FSH Controls or other commercially available controls
- 09P1540 Alinity i Multi-Assay Manual Diluent
- Alinity Trigger Solution
- Alinity Pre-Trigger Solution

· Alinity i-series Concentrated Wash Buffer

For information on materials required for operation of the instrument, **refer to the Alinity ci-series Operations Manual, Section 1.**

For information on materials required for maintenance procedures**, refer to the Alinity ci-series Operations Manual, Section 9.**

Assay Procedure

For a detailed description of how to run an assay, **refer to the Alinity ci-series Operations Manual, Section 5.**

· If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.

· To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

Maximum number of replicates sampled from the same sample cup: 10

Priority:

· Sample volume for first test: 75 µL

· Sample volume for each additional test from same sample cup: 25 µL

≤ 3 hours on the reagent and sample manager:

· Sample volume for first test: 150 µL

· Sample volume for each additional test from same sample cup: 25 µL

> 3 hours on the reagent and sample manager:

· Replace with a fresh aliquot of sample.

· Refer to the Alinity i FSH calibrator package insert and/or Alinity i FSH control package insert for preparation and usage.

· For general operating procedures, **refer to the Alinity ci-series Operations Manual, Section 5.**

· For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, **Section 9. Perform maintenance more frequently when required by laboratory procedures.**

Sample Dilution Procedures

Samples with an FSH value exceeding 150.00 mIU/mL (150.00 IU/L) are flagged with the code "> 150.00 mIU/mL" ("> 150.00 IU/L") and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

The system performs a **1:5** dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedure

Suggested dilution: 1:5

It is recommended that dilutions not exceed 1:5.

Add 20 µL of the sample to 80 µL of Alinity i Multi-Assay Manual Diluent.

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result. The result should be > 0.25 mIU/mL (> 0.25 IU/L) before the dilution factor is applied.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is less than
0.25 mIU/mL (0.25 IU/L), do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, **refer to the Alinity ci-series Operations Manual, Section 5.**

Each assay control must be tested to evaluate the assay calibration.

Once a calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

- A reagent kit with a new lot number is used.

Daily quality control results are outside of statistically-based quality control limits used to monitor and control system performance, as described in the Quality Control Procedures section of this package insert.

- If **statistically-based quality control limits are not available**, then the calibration should **not exceed a 30-day** limit for recalibration frequency.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

The recommended control requirement for the Alinity i FSH assay is that a single sample of each control level be tested once every day testing performed.

To establish statistically-based control limits, each laboratory should establish its own concentration target and ranges for new control lots at each clinically relevant control level. This can be accomplished **by assaying a minimum of 20 replicates over several (3-5) days** and using the reported results to establish the expected average (target) and variability about this average (range) for the laboratory. Sources of variation that should be included in this study in order to be representative of future system performance include:

- Multiple stored calibrations
- Multiple reagent lots
- Multiple calibrator lots
- Multiple processing modules (if applicable)

- Data points collected at different times of the day

Refer to published guidelines for information or general control recommendation, for example Clinical and Laboratory Standards Institute (CLSI) Document C24-A3 or other published guidelines, for general quality control recommendations.[17]

- If quality control results do not meet the acceptance criteria defined by laboratory QC procedure, sample results may be suspect. Follow the established quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information**, refer to the Alinity ci-series Operations Manual, Section 10**.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[18]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity i FSH assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted) to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, **refer to the Alinity ci-series Operations Manual, Section 5.**

Measuring Interval

Measuring interval is defined as the range of values in mIU/mL (IU/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity i FSH assay **is 0.11 to 150.00 mIU/mL** (0.11 to 150.00 IU/L).

LIMITATIONS OF THE PROCEDURE

- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- If the FSH results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as Alinity i FSH that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.[19, 20]
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.[21]

EXPECTED VALUES

This study was performed on the ARCHITECT i System.

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The manufacturers provided reference ranges are adopted.

The suggested normal range for the ARCHITECT FSH assay represents the FSH values obtained from 150 normal males, 34 post-menopausal females (not on hormone replacement therapy) and 44 normal cycling females. For this study, the follicular phase was defined as the period of time from 10 to 4 days prior to the mid-cycle peak. The luteal phase was defined as the period of time from 4 to 10 days following the mid-cycle peak. Cycle days were synchronized to the mid-cycle peak (the day when LH values are most elevated). The results are presented in the following table. (NOTE: 44 women participated in the study for serial blood draws. At the time of testing for ARCHITECT FSH, only 42 of the mid-cycle samples were available for testing. Samples from all 44 women were included in the Follicular and Luteal Phase expected values testing.)

		FSH Value (mIU/mL)	
			Range
	n	**Mean**	**(Central 95%)**
Males	150	3.37	0.95 - 11.95
Normally Menstruating Females			
Follicular Phase	144	4.95	3.03 - 8.08

		FSH Value (mIU/mL)	
	n	Mean	Range (Central 95%)
Mid-Cycle Peak	42	9.62	2.55 - 16.69
Luteal Phase	138	2.75	1.38 - 5.47
Post-Menopausal Females	34	59.71	26.72 - 133.41

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity i analyzer and the ARCHITECT i System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity i analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2.[22] Testing was conducted using 1 lot of the Alinity i FSH Reagent Kit, 1 lot of the Alinity i FSH Calibrators, and 1 lot of the Alinity i FSH Controls and 1 instrument. A three-member, calf serum-based panel was assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

		Mean mIU/mL	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	n	(IU/L)	SD	%CV	SD	%CV
Panel 1	115	5.07	0.091	1.8	0.097	1.9
Panel 2	120	25.73	0.435	1.7	0.496	1.9
Panel 3	120	79.77	1.785	2.2	2.136	2.7

[a]Includes within-run, between-run, and between-day variability.

Reproducibility

A study was performed based on guidance from CLSI EP05-A3.[23] Testing was conducted using 2 lots of Alinity i FSH reagents, 1 lot of Alinity i FSH Calibrators, and 1 lot of Alinity i FSH Controls across 6 Alinity i Instruments. Three serum based panels were tested in a minimum of
4 replicates, in 3 runs per instrument, for a minimum of 12 required measurements. The performance from a representative lot is shown in the following table.

Sample	n	Mean (mIU/mL)	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV
Panel 1	123	4.24	0.116	2.7	0.136	3.2	0.159	3.8
Panel 2	126	28.31	0.695	2.5	1.072	3.8	1.287	4.5
Panel 3	126	112.19	3.281	2.9	5.267	4.7	6.662	5.9

[a] Includes repeatability (within-run) and between-run variability.

[b] Includes repeatability (within-run), between-run, and between-instrument variability.

Accuracy by Recovery

This study was performed on the ARCHITECT i System.

Known concentrations of World Health Organization (WHO) 1st International Standard (IS) FSH 92/510 were added to 11 aliquots of human serum at 2 concentration levels (20 mIU/mL and 40 mIU/mL). The concentration of FSH was determined using the ARCHITECT FSH assay. The mean recovery of WHO 1st IS FSH is 96.05%.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.*24* Testing was conducted using 3 lots of the Alinity i FSH Reagent Kit on each of 2 instruments over a minimum of 3 days. The maximum observed Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below.

	mIU/mL (IU/L)
LoB[a]	0.01
LoD[b]	0.02
LoQ[c]	**0.11[d]**

[a]The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b]The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a total allowable error of 23% was met.

[d] The LoQ value of 0.11 mIU/mL (0.11 IU/L) reflects the maximum observed LoQ after excluding a single outlier replicate for the panel at 0.5 mIU/mL (0.5 IU/L) that was observed during this study. The maximum observed LoQ value including the single replicate outlier was 0.20 mIU/mL (0.20 IU/L).

Linearity

A study was performed based on guidance from CLSI EP06-A.*25*

This assay is linear across the measuring interval of **0.11 to 150.00 mIU/mL** (0.11 to 150.00 IU/L).

Cross-Reactants

This study was performed on the ARCHITECT i System.

The specificity of the ARCHITECT FSH assay was determined by studying the cross-reactivity of LH, TSH, and hCG. Aliquots of processed bovine serum were supplemented with
250 mIU/mL LH, 100 µIU/mL TSH, and 200 000 mIU/mL hCG and assayed for FSH. The cross-reactivity was calculated as a percent cross-reactivity and was shown to be 0.002% for LH, 0.043% for TSH and 0.001% for hCG.

Interference

Potentially Interfering Endogenous Substances

This study was performed on the ARCHITECT i System.

Potential interference from hemoglobin, bilirubin, triglycerides, and protein was studied in the ARCHITECT FSH assay. These compounds showed ≤ 10% interference in the ARCHITECT FSH assay at the levels indicated.

Potentially Interfering Substance	Interferent Level
Hemoglobin	≤ 500 mg/dL
Bilirubin	≤ 20 mg/dL
Triglycerides	≤ 3000 mg/dL
Protein	≤ 12 g/dL

Note: As the Alinity i FSH assay does not utilize a biotinylated antibody complex, there is no risk of potential interference to values reported by the assay when analyzing samples containing Biotin.

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[26]

	Sample Type	Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity i FSH vs ARCHITECT FSH	Serum	mIU/mL (IU/L)	136	1.00	0.09	0.98	0.25-146.84

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