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ADVIA® Chemistry XPT
Systems

Glucose Hexokinase_3 (GLUH_3)

Current Revision and Date[a]	Rev. G, 2019-07	
Product Name	ADVIA® Chemistry Glucose Hexokinase_3 (GLUH_3) Reagents	REF 05001429
Systems	ADVIA Chemistry XPT System	
Materials Required but Not Provided	Siemens Chemistry Calibrator Reagent container adapters Commercially available controls	REF 09784096 (T03-1291-62)
Specimen Types	Human serum, plasma (lithium heparin, potassium EDTA, sodium fluoride/potassium oxalate), urine, cerebrospinal fluid (CSF)	
Assay Principle	Hexokinase	
Assay Range	Serum: 4–700 mg/dL (0.2–38.9 mmol/L) Plasma: 4–700 mg/dL (0.2–38.9 mmol/L) Urine: 4–700 mg/dL (0.2–38.9 mmol/L) CSF: 4–700 mg/dL (0.2–38.9 mmol/L)	
Reagent Storage	2–8°C	
Reagent On-System Stability	60 days	
Reagent Code	74709	

[a] In Rev. E or later, a vertical bar in the margin indicates a technical update to the previous version.

Intended Use

For *in vitro* diagnostic use in the quantitative determination of glucose in human serum, cerebrospinal fluid (CSF), plasma and urine on ADVIA® Chemistry XPT systems. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and insulin overdose.

Summary and Explanation

This enzymatic assay is based on the method by Slein using hexokinase and glucose-6-phosphate dehydrogenase enzymes.[1,2]

Glucose is phosphorylated by adenosine triphosphate (ATP) in the presence of hexokinase. The glucose-6-phosphate that forms is oxidized in the presence of glucose-6-phosphate dehydrogenase causing the reduction of oxidized nicotinamide adenine dinucleotide (NAD) to reduced nicotinamide adenine dinucleotide (NADH).[1,2] The absorbance of NADH is measured as an endpoint reaction at 340/410 nm.

Principles of the Procedure

The ADVIA Chemistry Glucose Hexokinase_3 (GLUH_3) assay uses a two-component reagent. Sample is added to Reagent 1, which contains the buffer, ATP, and NAD. Absorbance readings of the sample in Reagent 1 are taken and are used to correct for interfering substances in the sample. Reagent 2 is added, which initiates the conversion of glucose and the development of absorbance at 340/410 nm. The difference between the absorbance in Reagent 1 and Reagent 2 is proportional to the glucose concentration.

Reaction Equation

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{Hexokinase}} \text{G6P} + \text{ADP}$$

$$\text{G6P} + \text{NAD}^{+} \xrightarrow{\text{G6PD}} \text{6 Phosphogluconate} + \text{NADH} + \text{H}^{+}$$

Reagents

Reagent	Description	Storage	Reagent Stability
REF 05001429	**ADVIA Chemistry Glucose Hexokinase_3 (GLUH_3) Reagents**		
Glucose Hexokinase_3 Reagent 1 GLUH_3 R1	68 mL in 70-mL containers ATP (4 mmol/L) NAD (3.21 mmol/L) NaN_3 (0.05%) Buffer	2–8°C	**Unopened:** Stable until the expiration date on product. **On-system:** 60 days
Glucose Hexokinase_3 Reagent 2 GLUH_3 R2	20 mL in 20-mL containers ATP (4 mmol/L) NAD (3.21 mmol/L) Hexokinase (microbial source) (> 6.25 U/mL) G6PD (microbial source) (> 11.25 U/mL) NaN_3 (0.09%) Buffer	2–8°C	**Unopened:** Stable until the expiration date on product. **On-system:** 60 days

Warnings and Precautions

Safety data sheets (MSDS/SDS) available on siemens.com/healthcare.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner, and in compliance with prevailing regulatory requirements.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For *in vitro* diagnostic use.

Preparing Reagents

All reagents are liquid and ready to use.

Before use, gently invert the capped reagent to disrupt bubbles and ensure homogeneity. If bubbles still exist or foam is present, use a clean transfer pipette to aspirate them from the reagent container prior to use.

Storing and Stability

Unopened reagents are stable until the expiration date printed on the product label when stored at 2–8°C. Do not freeze reagents.

Specimen Collection and Handling

Siemens Healthcare Diagnostics validated serum, plasma (lithium heparin, potassium EDTA, and sodium fluoride/potassium oxalate), urine, and cerebrospinal fluid (CSF) for the ADVIA Chemistry GLUH_3 assay.

Follow these guidelines for specimens used for this assay:

- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[3] Follow the instructions provided with your specimen collection device for use and processing.[4]
- Complete clot formation should take place before centrifugation.
- Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection.[5]
- Specimens should be free of particulate matter.
- Specimens should be as fresh as possible.

The purpose of handling and storage information is to provide guidance to users. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Procedure

Materials Provided

The following materials are provided:

Item	Contents	Number of Tests
REF 05001429	Reagent 1: 6 × 70-mL containers Reagent 2: 6 × 20-mL containers	6 × 660

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

Item	Description
REF 09784096 (T03-1291-62)	Siemens Chemistry Calibrator
REF 10316975	20-mL reagent container adapter for 40-mL slot
REF 10723030	20-mL reagent container adapter for 70-mL slot
	Commercially available control materials

Assay Procedure

Sampling, reagent delivery, mixing, and processing are automatically performed by the ADVIA Chemistry system.

For detailed information on performing the procedure, refer to the system operating instructions.

Preparing the System

For detailed information on preparing the system, refer to the system operating instructions.

Preparing the Samples

Before placing samples on the system, ensure that samples have the following characteristics:

- Samples are free of fibrin or other particulate matter.
- Samples are free of bubbles.

On-System Stability

The ADVIA Chemistry GLUH_3 reagents are stable on the system for 60 days.

Do not use reagents beyond the expiration date.

Performing Calibration

To calibrate the ADVIA Chemistry GLUH_3 assay, use the Siemens Chemistry Calibrator (REF 09784096 (T03-1291-62)).

Enter the lot-specific calibrator values that are provided with each lot of calibrator. Perform the calibration as described in the calibrator instructions for use.

Calibration Frequency

Calibrate the assay every 60 days.

Calibrate the assay after the following events:

- When the reagent lot number changes
- When a reagent pack is replaced by a new reagent pack with the same lot number, and the previous reagent pack was recalibrated during use
- After replacing critical optical or hydraulic components
- When indicated by quality control procedures

Individual laboratory quality control programs and procedures may require more frequent calibration.

Reagent Blank (RBL) Frequency

The ADVIA Chemistry system measures the RBL during assay calibration.

Run an additional RBL on the same reagent pack every 30 days.

Run an additional RBL when a reagent pack is replaced by a new reagent pack with the same lot number, and an additional reagent blank was run during use.

Note Use deionized water as the sample for the RBL in the ADVIA Chemistry GLUH_3 assay.

Performing Quality Control

Follow government regulations or accreditation requirements for quality control frequency.

At least once each day of use, analyze 2 levels (low and high) of a commercially available quality control (QC) material with known glucose concentrations.

A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme.

The actual frequency of control in a laboratory is based on many factors, such as workflow, system experience, and government regulation. Each laboratory should evaluate the controls based on the frequency established by their laboratory guidelines.

Also, assay controls under the following conditions:

- Whenever you use a new reagent lot
- Following any system maintenance, cleaning, or troubleshooting procedure
- After performing a new calibration or an additional reagent blank

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Taking Corrective Action

If the quality control results do not fall within the expected control range or within the laboratory's established values, do not report results. Take the following actions:

1. Determine and correct the cause of the unacceptable control results:
    a. Verify that the assay was performed according to the instructions for use.
    b. Verify that the materials are not expired.
    c. Verify that required maintenance was performed.
    d. Rerun the assay with fresh quality control samples, and confirm that quality control results are within acceptable limits before running patient samples.
    e. If the quality control results are not within acceptable limits, recalibrate the assay, and repeat the prior step.
    f. If necessary, contact your local technical support provider or distributor for assistance.
2. After corrective action is complete, repeat required testing of patient samples before reporting results.

Perform corrective actions in accordance with your established laboratory protocol.

Results

Calculation of Results

The system calculates and reports results based on the absorbance measurements of the test sample during the test, and of the calibrator(s) from calibration.

The instrument calculates the concentration of glucose in mg/dL (common units) or mmol/L (SI units).

Conversion factor: mg/dL × 0.0555 = mmol/L

Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

A number of substances cause physiological changes in serum, plasma (lithium heparin, potassium EDTA, and sodium fluoride/potassium oxalate), urine, or CSF analyte concentrations. A comprehensive discussion of possible interfering substances, their serum, plasma (lithium heparin, potassium EDTA, and sodium fluoride/potassium oxalate), urine, or CSF concentrations, and their possible physiological involvements is beyond the scope of this document. Consult the listed reference for specific details on known potential interfering substances.[6]

As with any chemical reaction, you must be alert to the possible effect on results of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.

Expected Values

The reference range for glucose hexokinase is listed in the following table.[7]

Sample Type		Reference Range
Serum/Plasma	Adult:	74–106 mg/dL (4.1–5.9 mmol/L)
	Newborn 1 day:	40–60 mg/dL (2.2–3.3 mmol/L)
	Newborn > 1 day:	50–80 mg/dL (2.8–4.4 mmol/L)
	Child:	60–100 mg/dL (3.3–5.6 mmol/L)
Urine		< 0.5 g/day (< 2.78 mmol/day)
CSF	Adult:	40–70 mg/dL (2.2–3.9 mmol/L)
	Infant/Child:	60–80 mg/dL (3.3–4.4 mmol/L)

Siemens provides this information for reference. As with all *in vitro* diagnostic assays, each laboratory should determine its own reference ranges for the diagnostic evaluation of patient results. Consider these values as a guideline only.

Performance Characteristics

Analytical Measuring Range

This assay is linear from 4–700 mg/dL (0.2–38.9 mmol/L) for serum, plasma, urine, and CSF.

Results that are below the assay range are flagged **< Conc Range**. You should report the test result as < 4 mg/dL (< 0.2 mmol/L) for serum, plasma, urine, and CSF.

Results that are above the assay range are flagged **> Conc Range**.

Extended Measuring Range

Siemens has validated an automatic rerun condition for this assay which extends the reportable range to 2100 mg/dL (116.6 mmol/L) for serum, plasma, urine, and CSF. You may configure the system to trigger automatic reruns. Rerun results will be flagged **Autorepeat**.

Sensitivity

The ADVIA Chemistry GLUH_3 assay performance at low levels was analyzed as described in CLSI protocol EP17-A2, and the limit of blank (LoB) and limit of detection (LoD) were determined.[8]

The LoB is the highest measurement result that is likely to be observed on a blank sample. The LoB for the ADVIA Chemistry GLUH_3 assay is 0 mg/dL (0.0 mmol/L) for serum, plasma, urine, and CSF (rounded to reportable digits).

The LoD is the smallest amount that this assay can reliably detect to determine presence or absence of an analyte. The LoD for the ADVIA Chemistry GLUH_3 assay is 4 mg/dL (0.2 mmol/L) for serum, plasma, urine and CSF.

The LoB and LoD values are determined with proportions of false positives (α) less than 5% and false negatives (β) less than 5%, based on 180 determinations with 120 blank and 60 low-level sample replicates.

Precision

The precision of the ADVIA Chemistry GLUH_3 assay was evaluated according to the CLSI protocol EP05-A2.[9] Each sample was assayed 3 times per run, 2 runs per day, for at least 10 days.

Precision: Common Units

			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Lab (Total)	
Specimen Type	N	Mean (mg/dL)	SD[a] (mg/dL)	CV[b] (%)	SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
Serum Control 1	60	86	0.3	0.4	0.6	0.7	0.6	0.7	0.9	1.0
Serum Control 2	60	289	0.7	0.3	1.9	0.7	1.2	0.4	2.4	0.8
Serum Pool 1	60	50	0.3	0.7	0.5	0.9	0.4	0.7	0.7	1.3
Serum Pool 2	60	121	0.5	0.4	1.3	1.1	0.0	0.0	1.4	1.2
Serum Pool 3	60	464	1.1	0.2	5.9	1.3	6.1	1.3	8.6	1.9
Urine Control 1	60	20	0.3	1.6	0.5	2.4	0.2	1.2	0.6	3.1
Urine Control 2	60	304	1.2	0.4	4.1	1.3	5.1	1.7	6.7	2.2
CSF Control 1	60	56	0.5	0.8	0.0	0.0	0.4	0.8	0.6	1.1
CSF Control 2	60	102	0.5	0.5	0.3	0.3	0.7	0.6	0.9	0.9

[a] SD = standard deviation

[b] CV = coefficient of variation

Precision: SI Units

			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Lab (Total)	
Specimen Type	N	Mean (mmol/L)	SD[a] (mmol/L)	CV[b] (%)	SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum Control 1	60	4.8	0.02	0.4	0.03	0.7	0.03	0.7	0.05	1.0
Serum Control 2	60	16.0	0.04	0.3	0.11	0.7	0.07	0.4	0.13	0.8
Serum Pool 1	60	2.8	0.02	0.7	0.02	0.9	0.02	0.7	0.04	1.3
Serum Pool 2	60	6.7	0.03	0.4	0.07	1.1	0.00	0.0	0.08	1.2
Serum Pool 3	60	25.8	0.06	0.2	0.33	1.3	0.34	1.3	0.48	1.9

			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Lab (Total)	
Specimen Type	N	Mean (mmol/L)	SD[a] (mmol/L)	CV[b] (%)	SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Urine Control 1	60	1.1	0.02	1.6	0.03	2.4	0.01	1.2	0.03	3.1
Urine Control 2	60	16.9	0.06	0.4	0.23	1.3	0.29	1.7	0.37	2.2
CSF Control 1	60	3.1	0.02	0.8	0.00	0.0	0.02	0.8	0.03	1.1
CSF Control 2	60	5.7	0.03	0.5	0.02	0.3	0.04	0.6	0.05	0.9

[a] SD = standard deviation

[b] CV = coefficient of variation

Actual results will vary depending on the study design, and on the sample and sample population used. Results obtained at individual laboratories may vary from the data provided.

Accuracy / Method Comparison

The performance of the ADVIA Chemistry GLUH_3 assay (y) was compared with the performance of the comparison assay on the indicated system (x).

Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sy.x	Sample Range
Serum	ADVIA 2400 GLUH_3	108	1.000	y = 1.02x + 1.0 mg/dL y = 1.02x + 0.05 mmol/L	4.4 mg/dL 0.24 mmol/L	4–648 mg/dL 0.2–36.0 mmol/L
Serum	ADVIA 1800 GLUH_3	108	0.999	y = 1.02x + 1.0 mg/dL y = 1.02x + 0.06 mmol/L	5.5 mg/dL 0.31 mmol/L	5–651 mg/dL 0.3–36.1 mmol/L
Plasma (Lithium Heparin)	ADVIA 1800 GLUH_3	67	1.000	y = 1.03x - 1.0 mg/dL y = 1.03x - 0.05 mmol/L	3.9 mg/dL 0.22 mmol/L	10–669 mg/dL 0.6–37.1 mmol/L
Plasma[a] (Lithium Heparin) ADVIA 1650/1800	ADVIA 1650/1800 GLUH_3 - Serum	88	1.000	y = 1.001x + 0.2 mg/dL y = 1.001x + 0.01 mmol/L	1.1 mg/dL 0.06 mmol/L	5–686 mg/dL 0.3–38.1 mmol/L
Plasma (Potassium EDTA)	ADVIA 1800 GLUH_3	50	1.000	y = 1.03x - 0.9 mg/dL y = 1.03x - 0.05 mmol/L	1.9 mg/dL 0.11 mmol/L	5–638 mg/dL 0.3–35.4 mmol/L
Plasma[a] (Potassium EDTA) ADVIA 1650/1800	ADVIA 1650/1800 GLUH_3 - Serum	87	1.000	y = 1.002x - 0.0 mg/dL y = 1.002x - 0.00 mmol/L	1.0 mg/dL 0.06 mmol/L	6–676 mg/dL 0.3–37.5 mmol/L
Plasma (NaFl-KOx)[b]	ADVIA 1800 GLUH_3	41	1.000	y = 1.03x - 1.9 mg/dL y = 1.03x - 0.10 mmol/L	2.1 mg/dL 0.12 mmol/L	10–676 mg/dL 0.6–37.5 mmol/L
Plasma[a] (NaFl-KOx)[b] ADVIA 1650/1800	ADVIA 1650/1800 GLUH_3 - Serum	56	0.999	y = 1.03x + 1.5 mg/dL y = 1.03x + 0.08 mmol/L	4.5 mg/dL 0.25 mmol/L	11–587 mg/dL 0.6–32.6 mmol/L
Urine	ADVIA 2400 GLUH_3	42	1.000	y = 1.02x - 0.7 mg/dL y = 1.02x - 0.04 mmol/L	1.9 mg/dL 0.11 mmol/L	4–677 mg/dL 0.2–37.6 mmol/L
Urine	ADVIA 1800 GLUH_3	43	1.000	y = 1.01x - 0.2 mg/dL y = 1.01x - 0.01 mmol/L	1.9 mg/dL 0.11 mmol/L	4–675 mg/dL 0.2–37.5 mmol/L

Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sy.x	Sample Range
CSF	ADVIA 2400 GLUH_3	57	1.000	y = 0.99x + 0.3 mg/dL y = 0.99x + 0.02 mmol/L	2.6 mg/dL 0.14 mmol/L	9–665 mg/dL 0.5–36.9 mmol/L
CSF	ADVIA 1800 GLUH_3	57	1.000	y = 0.99x - 0.8 mg/dL y = 0.99x - 0.04 mmol/L	2.0 mg/dL 0.11 mmol/L	10–665 mg/dL 0.6–36.9 mmol/L

[a] Matrix comparison. Correlations between serum and plasma samples on ADVIA 1650/1800 Chemistry systems are provided for reference.

[b] Sodium fluoride/Potassium Oxalate

The correlation of the assay may vary depending on the study design, comparable method, and sample population. Results obtained at individual laboratories may vary from the data provided.

Interferences

Siemens tested the following potential interferents and found the results shown below.

Interferences: Serum

Interferent	Interferent Level	Glucose Sample Concentration	Interference
Bilirubin (conjugated)	60 mg/dL (1026 µmol/L)	50 mg/dL (2.8 mmol/L)	NSI[a]
	60 mg/dL (1026 µmol/L)	184 mg/dL (10.2 mmol/L)	NSI
Bilirubin (unconjugated)	30 mg/dL (513 µmol/L)	50 mg/dL (2.8 mmol/L)	NSI
	45 mg/dL (769.5 µmol/L)	50 mg/dL (2.8 mmol/L)	+12.0%
	60 mg/dL (1026 µmol/L)	50 mg/dL (2.8 mmol/L)	+18.0%
	60 mg/dL (1026 µmol/L)	182 mg/dL (10.1 mmol/L)	NSI
Hemolysate (Hb)	1000 mg/dL (10 g/L)	50 mg/dL (2.8 mmol/L)	NSI
	1000 mg/dL (10 g/L)	186 mg/dL (10.3 mmol/L)	NSI
Lipemia[b] (triglycerides from Intralipid)	1000 mg/dL (11.3 mmol/L)	51 mg/dL (2.8 mmol/L)	NSI
	1000 mg/dL (11.3 mmol/L)	188 mg/dL (10.4 mmol/L)	NSI

[a] NSI = No significant interference. A percentage effect ≥ 10% is considered a significant interference.

[b] SI units calculated as triolein

Interferences: Urine

The following results are from the ADVIA 2400 Chemistry system using the same reagent, with assay conditions identical to those on the ADVIA Chemistry XPT system.

Interferent	Interferent Level	Glucose Sample Concentration	Interference
Ascorbic Acid	200 mg/dL (11.4 mmol/L)	33 mg/dL (1.8 mmol/L)	NSI[a]
Salicylate	50 mg/dL (3.6 mmol/L)	33 mg/dL (1.8 mmol/L)	NSI
Caffeine	50 mg/dL (2.6 mmol/L)	37 mg/dL (2.0 mmol/L)	NSI
Creatinine	500 mg/dL (44.2 mmol/L)	38 mg/dL (2.1 mmol/L)	NSI
Urea	500 mg/dL (83.3 mmol/L)	37 mg/dL (2.1 mmol/L)	NSI

[a] NSI = No significant interference. A percentage effect ≥ 10% is considered a significant interference.

Note There is poor correlation between turbidity and triglyceride concentration in a lipemic sample.[10]

Actual results will vary depending on the study design, the levels of the potential interferences tested, and the samples used. Results obtained at individual laboratories may vary from the data provided.

Standardization

The ADVIA Chemistry GLUH_3 assay is traceable to the Standard Reference Material 965a from the National Institute of Standards and Technology (NIST). Assigned values of Siemens Chemistry Calibrators are traceable to this standardization.

Technical Assistance

For customer support, please contact your local technical support provider or distributor.

siemens.com/healthcare

References

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
IVD	*In vitro* diagnostic medical device	REF REF	Catalog number
	Legal manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Mark	CE 0088	CE Mark with identification number of notified body
	Consult instructions for use		Biological risk
	Keep away from sunlight and heat		Temperature limitation
	Lower limit of temperature		Upper limit of temperature
	Do not freeze (> 0°C)		Up
	Use by	Σ (n)	Contains sufficient for (n) tests
	Recycle	PRINTED WITH SOY INK	Printed with soy ink
Rev.	Revision	YYYY-MM-DD	Date format (year-month-day)
LOT	Batch code	**RxOnly**	Prescription Device (US only)

Trademarks

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