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Changes: § 4
Deletions: §

LIAISON® Thymidine Kinase (REF 310960)

1. INTENDED USE

The DiaSorin LIAISON® Thymidine Kinase is a quantitative immunoassay for the *in vitro* determination of Thymidine Kinase (TK) activity in human serum or EDTA plasma. Determination of serum Thymidine Kinase activity is useful for prognosis and monitoring of patients with hematological malignancies.

Assay results should be used in conjunction with other clinical and laboratory data to assist in the diagnosis and management of conditions involving hematologic malignancies. The test has to be performed on the LIAISON® Analyzer family*.

This assay is intended for *in vitro* diagnostic use.

2. SUMMARY AND EXPLANATION OF THE TEST

TK is involved in the synthesis of DNA and catalyses the phosphorylation of thymidine to thymidine monophosphate (1). The activity of TK increases dramatically during the S-phase of the cell cycle. Its activity has been shown to be a reliable marker of the proliferative activity of tumor cells (2,3). TK in human cells occurs as two isoenzymes, a cytosolic (TK1) and a mitochondrial (TK2) form. Only the level of TK1 is related to the cell cycle (4). A large number of clinical studies have reported elevated TK levels in a variety of neoplasias. However, in most studies, TK has been used for prognosis and treatment monitoring of hematological malignancies. It has been shown that elevated levels of serum TK predict a high risk of disease progression in low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia (CLL). In CLL, TK seems to provide prognostic information that is independent of the Binet staging system (5,6,7) and TK adds independent prognostic information to the criteria defining smoldering CLL (8). Furthermore serum TK determinations may help to distinguish between patients with multiple myeloma (MM) and those with monoclonal gammopathy of undetermined significance (MGUS) (9). In addition, serum TK correlates with the clinical staging and gives prognostic information. Very high TK values are reported in patients with acute leukemia. Studies have shown that serum-TK may indicate the aggressiveness of the leukemic cells and predict response to therapy and the length of survival (10,11).

3. PRINCIPLE OF THE PROCEDURE

The LIAISON® Thymidine Kinase assay is an indirect, modified 2-step, competitive chemiluminescence immunoassay (CLIA) for the quantitative determination of TK in human serum and EDTA plasma. The assay utilizes an initial enzymatic reaction in which TK in the sample converts AZT (3'-azido-3'-deoxythymidine) to AZTMP (3'-azido-3'-deoxythymidine mono phosphate), this is followed by a competitive immunoassay for the quantitative determination of AZTMP. The amount of AZT converted to AZTMP is a measure of the amount of TK present in the sample. In the assay, 50 µL of sample is incubated with 100 µL of Assay Buffer 1, 20 µL of Assay Buffer 2, and 20 µL of paramagnetic particles coated with anti-AZTMP polyclonal antibody. Rabbit anti-goat IgG, then anti-AZTMP goat polyclonal is coated to the solid phase. This is incubated for 40 minutes and then 100 µL of tracer, an AZTMP analogue conjugated to an isoluminol derivative is added. During the first incubation, AZTMP binds to the solid phase. In the second incubation, the tracer conjugate competes for binding with the AZTMP in the solution. After a 20 minute incubation, the unbound material is removed with a wash cycle. The starter reagents are then added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of TK present in calibrators, controls, or samples.

4. MATERIALS PROVIDED

Reagent Integral

Magnetic Particles (2.4 mL)	[SORB]	Magnetic particles coated with rabbit and goat antibodies, buffer, 0.1% BSA, surfactant , 0.09% sodium azide, pH 7.4.
Conjugate (12 mL)	[CONJ]	Isoluminol derivative in buffer, 0.2% BSA, 0.09% NaN ₃ , pH 7.4.
Assay Buffer 1 (12 mL)	[BUF AS]	Buffer, pH 7.4 with cofactors and rabbit and goat IgGs, surfactant , 0.1% ProClin® 300
Assay Buffer 2 (2.5 mL)	[BUF AS]	Buffer, pH 4.5
Number of Tests		100

ProClin is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

All reagents are supplied ready to use. The order of reagents reflects the layout of containers in the Reagent Integral

*(LIAISON®, LIAISON® XL)

Additional components not on the Reagent Integral

Calibrator 1 (2 x 1.0 mL) Lyophilized	CAL1	Human serum, 0.09% NaN ₃ and TK. Reconstitute in 1 mL distilled or deionized water. Aliquot and store reconstituted calibrator at –20°C.
Calibrator 2 (2 x 1.0 mL) Lyophilized	CAL2	Human serum, 0.09% NaN ₃ and TK. Reconstitute in 1 mL distilled or deionized water. Aliquot and store reconstituted calibrator at –20°C.

Standardization: The calibrator concentrations (U/L) are referenced to an in-house standard preparation.

Materials required but not provided (system related)

LIAISON® XL Analyzer	LIAISON® Analyzer
LIAISON® Wash/System Liquid (REF 319100)	LIAISON® Wash/System Liquid (REF 319100)
LIAISON® XL Waste Bags (REF X0025)	LIAISON® Waste Bags (REF 450003)
LIAISON® XL Cuvettes (REF X0016)	LIAISON® Module (REF 319130)
LIAISON® XL Starter Kit (REF 319200)	LIAISON® Starter Kit (REF 319102)
LIAISON® XL Disposable Tips (REF X0015)	LIAISON® XL Starter Kit (REF 319200)
	LIAISON® Cleaning Kit (REF 310990)
	LIAISON® Light Check 12 (REF 319150)

Additional required materials:

LIAISON® Thymidine Kinase Control Set (**REF** 310961)

Additional recommended materials :

LIAISON® Thymidine Kinase Specimen Diluent (**REF** 310962)

5. WARNINGS AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE – Not for internal or external use in humans or animals.

GENERAL SAFETY:

- All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Avoid contact with skin, eyes or mucous membranes. Follow good industrial hygiene practices during testing.
- Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
- Do not pipet solutions by mouth.
- Avoid direct contact with all potentially infectious materials by wearing lab coat, protective eye/face wear and disposable gloves.
- Wash hands thoroughly at the end of each assay.
- Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach solution (containing 0.5% sodium hypochlorite) and disposed of as though potentially infectious.
- Waste materials should be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country.
- Do not use kits or components beyond the expiration date given on the label.

CHEMICAL HAZARD AND SAFETY INFORMATION: Reagents in this kit are classified in accordance with US OSHA Hazard Communication Standard; individual US State Right-to-Know laws; Canadian Centre for Occupational Health and Safety Controlled Products Regulations; and applicable European Union directives (see Material Safety Data Sheet for additional information).

REAGENTS CONTAINING HUMAN SOURCE MATERIAL:

Warning – Treat as potentially infectious. Each serum/plasma donor unit used in the preparation of this product has been tested by a U.S. FDA approved method and found non-reactive for the presence of the antibody to Human Immunodeficiency Virus 1 and 2 (HIV 1/2), the Hepatitis B surface antigen (HBsAg), and the antibody to Hepatitis C (HCV). While these methods are highly accurate, they do not guarantee that all infected units will be detected. This product may also contain other human source diseases for which there is no approved test. Because no known test method can offer complete assurance that HIV, Hepatitis B Virus (HBV) and HCV or other infectious agents are absent, all products containing human source material should be handled following universal precautions; and as applicable in accordance with good laboratory practices as described in the Centers for Disease Control and the National Institutes of Health current manual, Biosafety in Microbiological and Biomedical Laboratories (BMBL); or the World Health Organization current edition, Laboratory Biosafety Manual.

GHS/CLP:

	ProClin®	Sodium Azide
CAS No.:	55965-84-9	26628-22-8
Reagents:	BUFAS	SORB CONJ CAL1 CAL2
Classification:	Skin sensitization, Category 1 Aquatic Chronic, Category 3	None required
Signal Word:	Warning	None required
Pictogram:	 GHS07 – Exclamation mark	None required
Hazard Statements:	H317 – May cause an allergic skin reaction. H412 – Harmful to aquatic life with long lasting effects.	None required
Precautionary Statements:	P261 – Avoid breathing mist or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves and clothing, and eye protection.	None required

REAGENTS CONTAINING SODIUM AZIDE: Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control and Prevention, Atlanta, GA, 1976

6. PREPARATION OF THE REAGENT INTEGRAL

Please note the following important reagent handling precautions:

6.1 Resuspension of magnetic particles

Magnetic particles must be completely resuspended before the integral is placed on the instrument. Follow the steps below to ensure complete suspension:

- Before the seal is removed, rotate the small wheel at the magnetic particle compartment until the colour of the suspension has changed to brown. Gentle and careful side-to-side mixing may assist in the suspension of the magnetic particles (avoid foam formation). Visually check the bottom of the magnetic particle vial to confirm that all settled magnetic particles have resuspended.
- Repeat as necessary until the magnetic particles are completely resuspended.
- After removal of the seal carefully wipe the surface of each septum to remove residual liquid if necessary.

6.2 Foaming of reagents

- In order to ensure optimal performance of the integral, foaming of reagents should be avoided. Adhere to the recommendation below to prevent this occurrence: Visually inspect the reagents to ensure there is no foaming present before using the integral. If foam is present after re-suspension of the magnetic particles, place the integral on the instrument and allow the foam to dissipate. The integral is ready to use once the foam has dissipated and the integral has remained onboard and mixing.

6.3 Loading of integral into the reagent area

LIAISON® Analyzer

- Place the integral into the reagent area of the analyzer with the bar code label facing left and let it stand for 30 minutes before using. The analyzer automatically stirs and completely resuspends the magnetic particles.
- Follow the analyzer operator's manual to load the specimens and start the run.

LIAISON® XL Analyzer

- LIAISON® XL Analyzer is equipped with a built-in solid-state magnetic device which aids in the dispersal of microparticles prior to placement of a reagent integral into the reagent area of the analyzer. Refer to the analyzer operator's manual for details.
 - a. Insert the reagent integral into the dedicated slot.
 - b. Allow the reagent integral to remain in the solid-state magnetic device for at least 30 seconds (up to several minutes). Repeat as necessary.
- Place the integral into the reagent area of the analyzer with the label facing left and let it stand for 15 minutes before using. The analyzer automatically stirs and completely resuspends the magnetic particles.
- Follow the analyzer operator's manual to load the specimens and start the run.

7. STORAGE AND STABILITY OF THE REAGENT INTEGRAL

Upon receipt, the reagent integral must be stored in an upright position to facilitate re-suspension of magnetic particles. When the reagent integral is stored unopened the reagents are stable at 2-8°C up to the expiry date. Do not freeze. The reagent integral should not be used past the expiry date indicated on the kit and reagent integral labels. After use, the reagent integral should be stored on the LIAISON® or returned to storage at 2-8°C. The opened Reagent Integral, when stored on board or at 2-8°C, has minimum stability of 4 weeks. After this period, it is still possible to keep on using the Reagent Integral provided that the controls are found within the expected ranges.

8. SPECIMEN COLLECTION AND PREPARATION

Human serum or EDTA plasma should be used. Fasting samples are recommended, but not required. Blood should be collected aseptically by venipuncture, allowed to clot, and the serum separated from the clot as soon as possible. No additives or preservatives are required to maintain integrity of the sample. Samples having particulate matter, turbidity, lipemia, or erythrocyte debris may require clarification by filtration or centrifugation before testing. Grossly hemolyzed or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination should not be tested. Check for and remove air bubbles before assaying. Samples are stable for 48 hours at 2-8°C, otherwise they should be stored frozen (-20°C or below). Specimens may be stored in glass or plastic vials. The minimum volume required is 200 µL. If samples are stored frozen, mix thawed samples well before testing. Avoid repeated freeze-thaw cycles.

9. CALIBRATION

Individual LIAISON® Thymidine Kinase Reagent Integrals contain specific information for calibration of the particular Reagent Integral lot. Test of assay specific calibrators allows the detected relative light units (RLU) values to adjust the assigned master curve. Each calibration solution allows 3 calibrations to be performed. Recalibration in triplicate is mandatory whenever at least 1 of the following conditions occurs:

- With each new lot of reagents (Reagent Integral or Starter Reagents).
- The previous calibration was performed more than 14 days prior.
- Quality control results are out of your acceptable range.
- The Analyzer has been serviced.

Measuring Range. The DiaSorin LIAISON® Thymidine Kinase Assay measures between 0.5 U/L and 100 U/L. The lowest reportable value is 0.5 U/L. Values below 0.5 U/L should be reported as < 0.5 U/L. The highest reportable value without dilution is 100 U/L. Any samples higher than the reportable range should be diluted in the DiaSorin LIAISON® Thymidine Kinase Specimen Diluent ([REF] 310962), re-assayed and recalculated. See section 17.8.

10. Calibrators Level 1 and 2

The LIAISON® Thymidine Kinase calibrators are supplied lyophilized. Reconstitute each vial with 1.0 mL of distilled or deionized water. Allow the vials to stand for a minimum of 10 minutes at room temperature, mix gently by inversion. Once calibrators are mixed, transfer a minimum of 300 µL to glass or plastic sample tubes. Affix the appropriate bar code labels to the tubes, place in the sample rack with the bar codes showing outward and slide rack onto the analyzer. Calibrate the assay as described in the Operator's Manual.

TK calibrators have been shown to be stable for 1 hour on board the analyzer or for 4 hours on ice. Remaining reconstituted calibrators should be aliquoted into vials with a minimum of 300 µL and frozen immediately. Frozen calibrators are stable up to 1 month and can be used through 3 freeze thaw cycles. When thawing frozen aliquot, mixing is required.

Calibrator and reagent integral lot number are lot specific. Do not use calibrators matched with a different reagent lot in the same assay.

11. ASSAY PROCEDURE

To ensure proper test performance, strictly adhere to the operating instructions of the analyzer.

LIAISON® Analyzer. Each test parameter is identified via the bar codes on the reagent integral label. In the event that the barcode label cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral; contact your local DiaSorin technical support for instruction.

LIAISON® XL Analyzer. Each test parameter is identified via information encoded in the reagent integral Radio Frequency IDentification transponder (RFID Tag). In the event that the RFID Tag cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral; contact your local DiaSorin technical support for instruction.

For details, refer to the analyzer operator's manual.

The analyzer operations are as follows:

LIAISON® Analyzer:

1. Dispense 50 µL sample, calibrator, or control into reaction module.
2. Dispense Assay Buffer 1, Assay Buffer 2, and magnetic particles into reaction module.
3. Incubate 40 minutes.
4. Dispense conjugate into reaction module.
5. Incubate 20 minutes.
6. Wash with Wash/System liquid.
7. Add the Starter Reagents and measure the light emitted.

LIAISON® XL Analyzer:

1. Dispense Assay Buffer 2, and magnetic particles into reaction module.
2. Dispense 50 µL sample, calibrator, or control into reaction module.
3. Dispense Assay Buffer 1 into reaction module.
4. Incubate 40 minutes.
5. Dispense conjugate into reaction module.
6. Incubate 20 minutes.
7. Wash with Wash/System liquid.
8. Add the Starter Reagents and measure the light emitted.

12. QUALITY CONTROL

Quality control is required to be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. It is recommended that the user refer to CLSI C24-A3, and 42 CFR 493.1256 (c) for guidance on appropriate quality control practices.

LIAISON® Thymidine Kinase controls are intended to monitor for substantial reagent failure. LIAISON® controls should be run in singlicate to monitor the assay performance. If control values lie within the expected ranges provided on the certificate of analysis, the test is valid. If control values lie outside the expected ranges, the test is invalid and patient results cannot be reported. Assay calibration should be performed if a control failure is observed and controls and patient specimens must be repeated.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate value ranges should be established for all quality control materials used.

The range of concentrations of each control is reported on the certificate of analysis and indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs.

13. INTERPRETATION OF RESULTS

The analyzer automatically calculates the concentration of TK in the sample. This concentration is expressed in U/L (Units/Liter).

Calibrators and controls may give different RLU or dose results on LIAISON® and LIAISON® XL, but patient results are equivalent.

14. LIMITATIONS OF THE PROCEDURE

1. A skillful technique and strict adherence to the instructions are necessary to obtain reliable results.
2. Bacterial contamination of samples or repeated freeze-thaw cycles may affect the test results.
3. Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.

Integrals may not be exchanged between analyzer types (LIAISON® and LIAISON® XL). Once an integral has been introduced to a particular analyzer type, it must always be used on that analyzer until it has been exhausted. Due to traceability issues resulting from the above statement, patient follow-ups may not be concluded between analyzer types. These must be accomplished on one particular analyzer type (either LIAISON® or LIAISON® XL).

15. EXPECTED VALUES

Serum samples from 98 subjects in apparent good health were analyzed in duplicate by the LIAISON® Thymidine Kinase procedure.

Population (N)	Mean TK	Observed 5-95 % Range
healthy (n=98)	4.3 U/L	2.0 – 7.5 U/L

Consider these limits as guidelines only. Each laboratory should establish its own reference ranges.

Patients with hematological malignancies:

Population (N)	Mean TK	Observed 5-95 % Range
Non-Hodgkins-Lymphoma		
Total (n=172)	24.8 U/L	0.9 – 101 U/L
Indolent (n=33)	9.9 U/L	1.5 – 26.0 U/L
Agressive (n=54)	38.4 U/L	<0.5 – 227 U/L
Myeloma (n=95)	20.5 U/L	<0.5 – 104 U/L
MGUS (n=17)	2.6 U/L	<0.5 – 6.9 U/L
Hodgkin's Lymphoma (n=23)	12.8 U/L	3.3 – 45.9 U/L
Benign infections (n=43)	7.3 U/L	2.9 – 17.9 U/L
Benign disease (n=20)	5.3 U/L	1.1 – 10.8 U/L

MGUS: monoclonal gammopathy of unknown significance.

Consider these limits as guidelines only. Each laboratory should establish its own reference ranges.

16. SPECIFIC PERFORMANCE CHARACTERISTICS

16.1 Analytical Sensitivity: The analytical sensitivity, defined as the minimum detectable dose distinguishable from 0 by 2 Standard Deviations, is ≤ 0.5 U/L.

16.2 Functional Sensitivity: The functional sensitivity is defined as the concentration at which the %CV exceeds 20%. The derived functional sensitivity from the regression analysis of the precision profile is ≤ 5 U/L.

16.3 Precision: Precision was evaluated following CLSI EP 5-A2. 10 samples, containing different concentrations of analyte, were assayed in duplicate, 2 runs per day, over 20 operating days, to determine the repeatability and reproducibility of the assay (i.e. within- and between-assay variability).

Repeatability	1	2	3	4	5	6	7	8	9	10
Mean (U/L)	6.4	11.9	14.2	20.0	32.2	36.6*	41.8*	43.1	48.4	85.3
IntraSD (U/L)	0.6	0.8	0.7	1.0	1.2	1.8	1.6	1.7	1.5	3.4
Coefficient of Variance (%)	9.2	6.6	5.1	5.0	3.9	4.9	3.8	3.9	3.1	4.0

Reproducibility	1	2	3	4	5	6	7	8	9	10
Mean (U/L)	6.4	11.9	14.2	20.0	32.2	36.6*	41.8*	43.1	48.4	85.3
Grand SD (U/L)	1.2	1.3	1.4	2.1	1.9	2.9	2.3	5.1	3.7	7.6
Coefficient of Variance (%)	19.5	10.7	10.3	10.7	5.8	8.0	5.4	12.1	7.8	9.0

*diluted 1:3 in specimen diluent

16.4 Precision with LIAISON® XL Analyzer: Precision was evaluated following CLSI EP 5-A2. 10 samples, containing different concentrations of analyte, were assayed in duplicate, 2 runs per day, over 20 operating days, to determine the repeatability and reproducibility of the assay (i.e. within- and between-assay variability).

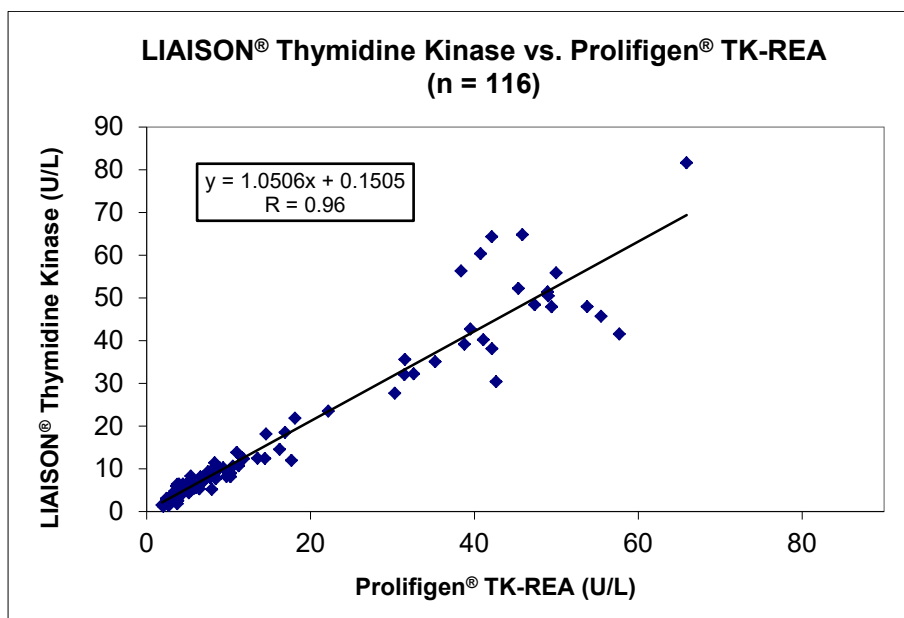
Repeatability	1	2	3	4	5	6	7	8	9	10
Mean (U/L)	11.6	46.9	5.8	10.0	16.4	34.6	39.2	85.0	39.3*	52.5*
IntraSD (U/L)	0.8	2.3	0.4	0.4	0.5	1.2	1.2	2.3	1.6	1.7
Coefficient of Variance (%)	6.8	4.9	6.7	4.5	3.2	3.4	3.0	2.7	4.0	3.3

Reproducibility	1	2	3	4	5	6	7	8	9	10
Mean (U/L)	11.6	46.9	5.8	10.0	16.4	34.6	39.2	85.0	39.3*	52.5*
Grand SD (U/L)	1.23	3.76	0.70	1.02	1.51	2.45	2.70	5.42	3.33	4.20
Coefficient of Variance (%)	10.6	8.0	12	10.2	9.2	7.1	6.9	6.4	8.5	8.0

*diluted 1:3 in specimen diluent

16.5 Method Comparison:

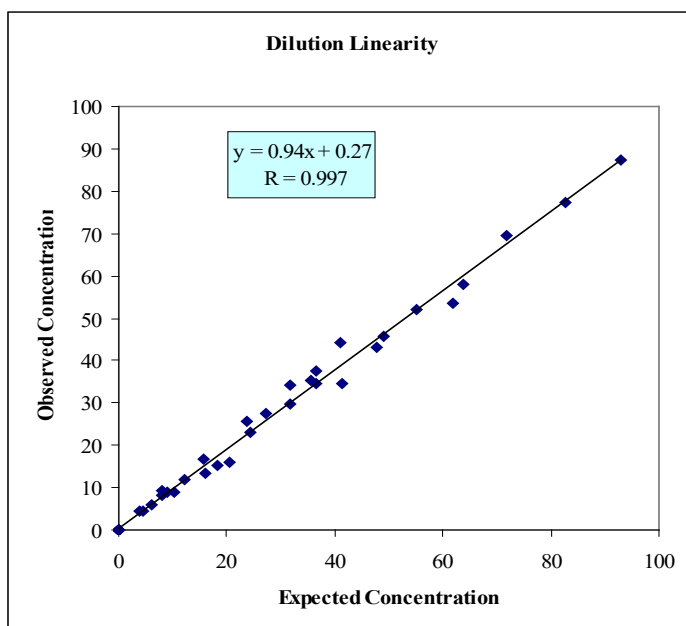
A total of 116 clinical samples were tested by LIAISON® Thymidine Kinase and by the Prolifigen® TK-REA method and yielded the following comparison. $\text{LIAISON}^{\circledR} = 1.0506 \text{ REA} + 0.1505$; $R = 0.96$.



16.6 Trueness Dilution Test:

The assay trueness has been verified by the dilution test.

5 spiked patient samples were diluted and analyzed. The results were analyzed as a linear regression of the Expected vs. Observed values. The resulting regression equation is: $\text{Observed} = 0.94 (\text{Expected}) + 0.27$; $r = 0.997$.



16.7 Recovery

5 high concentration spiked samples and 5 low concentration clinical samples were analyzed neat in 5 replicates. Recovery samples are prepared by mixing defined ratios of the high and low samples and analyzing these in replicates of 5.

	Defined	Expected	Observed	% Recovery
High Sample 1 (HS1)	108.5			
2 HS1 : 1 LS1		80.7	84.2	104%
1 HS1 : 1 LS1		66.5	66.3	100%
1 HS1 : 2 LS1		52.2	50.8	97%
Low Sample 1 (LS1)	24.5			
High Sample 2 (HS2)	81.4			
2 HS2 : 1 LS2		56.8	52.1	92%
1 HS2 : 1 LS2		44.2	41.9	95%
1 HS2 : 2 LS2		31.5	31.1	99%
Low Sample 2 (LS2)	7.0			
High Sample 3 (HS3)	54.0			
2 HS3 : 1 LS3		38.5	38.5	100%
1 HS3 : 1 LS3		30.5	33.5	110%
1 HS3 : 2 LS3		22.6	24.6	109%
Low Sample 3 (LS3)	7.1			
High Sample 4 (HS4)	44.8			
2 HS4 : 1 LS4		33.4	33.4	100%
1 HS4 : 1 LS4		27.5	27.6	101%
1 HS4 : 2 LS4		21.6	21.8	101%
Low Sample 4 (LS4)	10.1			
High Sample 5 (HS5)	42.8			
2 HS5 : 1 LS5		30.9	30.7	99%
1 HS5 : 1 LS5		24.9	25.3	102%
1 HS5 : 2 LS5		18.9	18.8	100%
Low Sample 5 (LS5)	7.24			
Mean				101%
SD				4.7%

16.8 Dilution of high sample (> 100 U/L)

Samples that read greater than 100 U/L should be diluted using the LIAISON® Thymidine Kinase Specimen Diluent. The recommended dilution is (1:3) 200 uL diluent + 100 uL patient sample. Mix the dilution well, re-assay, and calculate the final concentration by multiplying by the dilution factor.

16.9 Interfering substances:

Controlled studies of potentially interfering substances showed that the assay performance was not affected by cholesterol (up to 500 mg/dL), hemolysis (up to 200 mg/dL), bilirubin (up to 20 mg/dL), and triglyceride (up to 3000 mg/dL).

17. References

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