Diagnostic Reagents Limited

UK CA

Normal and Abnormal IQC Plasmas

Catalogue Number: IQCN130 (Normal) Lot No.
IQCM140 (Abnormal 1) Lot No.
IQCS150 (Abnormal 2) Lot No.

For *in vitro* diagnostic use only.

Intended Use

Normal and Abnormal Internal Quality Control (IQC) plasmas are designed for monitoring the performance and methodology of *In vitro* diagnostic reagent test systems. These tests include the Prothrombin Time (PT) & Activated Partial Thromboplastin Time (APTT).

Summary and Principle

The PT & APTT are tests performed to evaluate the efficacy of the haemostatic pathways. They help identify patients at risk of bleeding from acquired or inherited deficiency states and are used in the therapeutic control of both Oral Anticoagulant Therapy (OAT) and Heparin. Amongst other uses, they are conversely used to detect thrombotic risk associated with the Lupus Anticoagulant and resistance to Activated Protein C (APC resistance).

Diagen coagulation control plasmas are manufactured from citrated blood and designed to be used in the same way as test plasma. Their function is to provide an **Internal Quality Control (IQC)** system to monitor the performance of the **test system** and to help eradicate erroneous results caused by reagent, instrumentation or other component malfunction.

Both normal & abnormal control plasmas should be used several times a day, before and during patient test runs to give assurance that all aspects of the test system are performing to pre-defined parameters. The use of more than one control plasma makes it easier to identify possible causes of error.

Normal	Abnormal 1	Abnormal 2
PT	PT	PT
APTT	APTT	APTT

If all PT & APPT results are out of range, it suggests probable instrument malfunction.

If all PTs are out of range but all APTTs are in range, it suggests a fault with the PT reagent.

If all APTTs are out of range but all PTs are in range, it suggests a fault with the APTT reagent.

If individual PTs and or APTTs are out of range, it would suggest a fault with an individual IQC control plasma.

Reagent

IQC Plasma **10 vials**

Diagen IQC plasmas are made from citrated human plasma, lyophilized in the presence of glycine, buffers and stabilizers. They are manufactured to give expected values for PT and APTT in three ranges; normal, mild coagulation abnormality (Abnormal 1) and severe coagulation abnormality (Abnormal 2).

For reconstitution, add 0.5 mL of distilled water to the vial, mix gently and allow 5 - 10 for complete solution before use.

Warnings and precautions

POTENTIAL BIOHAZARD MATERIAL.

IQC Plasma is of human origin. All donor units used in production of this product have been found negative for anti HIV, anti HCV, HBsAg and Syphilis by approved methods. However, all plasma of human origin should be considered as potentially infectious and handled appropriately.

Please refer to the relevant SDS Sheet for handling and safety procedures. Dispose of all waste materials according to the stated international, national and local regulations.

Procedure

Materials Provided:

IQC plasma.

Cat. No.

IQCN130 - Normal PT and APTT Control Plasma.
IQCM140 - Mildly Abnormal PT and APTT Control Plasma.
IQCS150 - Severely Abnormal PT and APTT Control Plasma.

Materials and equipment required, but not provided:

1. Reagents for Activated Partial Thromboplastin Time (APTT) and Prothrombin time (PT) tests.
2. General routine coagulation equipment.
3. Pipette delivering 0.5 mL.
4. Distilled water.

Manual and Automated Technique

Follow instructions supplied with both reagents and instrument manufacturer's protocol.

Reporting Results

Each laboratory should assign reference values and ranges **to each new lot of control plasma and reagents** by replicate testing over several days. These values should then be used to monitor the test system performance over the lifetime of both the IQC plasma and reagents. The most common method of reporting is to use the Levey - Jennings chart [(1)]. It shows the mean value obtained at initial testing and the upper and lower limits, usually 2 standard deviations (S.D), which should encompass 95.5% of results obtained. Using the chart, trends can be detected before clinically relevant erroneous results are obtained. The graph below (Figure 1.) shows an example of a Levey - Jennings chart for the APTT with IQC Abnormal 1.

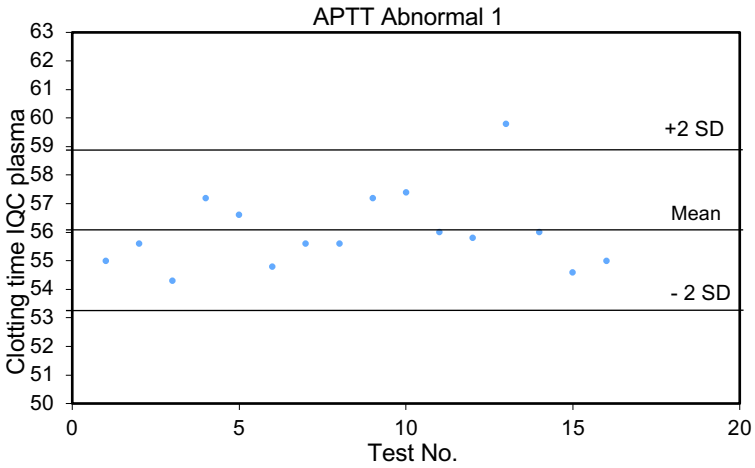


Figure 1. A Levey – Jennings Chart with two standard deviations either side of the mean clotting time.

Expected Results

IQC plasmas are manufactured to conform to the results shown in the certificate of analysis (page 4) using the Diagen manual methods:

Limitations

IQC plasmas are manufactured from citrated whole blood. The abnormal controls are artificially depleted of clotting factors and so, unlike plasma for OAT patients, may give different INR values when comparing PT reagents from different manufacturers. APTT reagents of other manufacturers may also give different ratios due to their variation in sensitivity to individual clotting factors.

Storage and stability

The unopened freeze dried vials are best stored deep frozen, but may be stored for up to 3 years at 4° or below without deterioration.
Once reconstituted the contents of the vial are then stable for up to 8 hours when held at 2 - 8°C.

Packaging

10 x 0.5 mL

Performance characteristics

IQC plasmas, with Diagen reagents, using the manual technique, gave the following within run & between run CVs%.

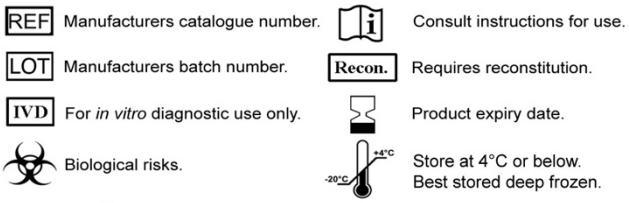
Within run	PT CV%	APTT CV%
Normal	0.86	0.68
Abnormal 1	1.27	1.05
Abnormal 2	1.85	1.73

Between run	PT CV%	APTT CV%
Normal	1.22	1.06
Abnormal 1	1.70	1.66
Abnormal 2	1.95	1.87

References

1) Levey S, Jennings ER The use of control charts in the clinical laboratory. Am J Clin Pathol 1950; 20; 1059 – 1066.

Key guide to symbols



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Diagnostic Reagents Limited is a BS EN ISO13485:2016 certified company

IQCIFU-002 Revision -

Certificate of Analysis (CoA)

Using Diagen reagents with the manual methods:

	IQC Plasmas		
	Normal	Abnormal 1	Abnormal 2
Code No:	IQCN130	IQCM140	IQCS150
lot No.	KP100	AB1-82	AB2-79

Reagents:

PT

	Calcium Thromboplastin :		
	Normal	Abnormal 1	Abnormal 2
INR	0.97	1.82	2.83
Range	0.92-1.02	1.62-2.02	2.55-3.11

	Freeze dried Rabbit Brain Thromboplastin:		
	Normal	Abnormal 1	Abnormal 2
INR	1.02	1.78	2.67
Range	0.97-1.07	1.68-2.08	2.3-3.1

APTT

	Kaolin Platelet Substitute Mixture:		
	Normal	Abnormal 1	Abnormal 2
Clotting time (secs)	46.5	54.8	88.2
RATIO*	1.08	1.34	2.20
Range	1.01-1.15	1.22-1.52	2.0-2.4
Range (secs)	43.5-49.5	50-62	80-96

	Micronised Silica Platelet Substitute Mixture:		
	Normal	Abnormal 1	Abnormal 2
Clotting time (secs)	36.5	49.0	71.2
RATIO*	1.01	1.36	1.93
Range	0.95-1.07	1.22-1.50	1.70-2.10

*** Clotting time divided by mean normal clotting time**

IQC Plasma vials are labelled with the INR and APTT ratio obtained using the Diagen Calcium Thromboplastin (PT reagent) and Kaolin Platelet substitute mixture (APTT reagent) using the manual methods.