Diagnostic Reagents Limited

UK CA

Reagent / System Control Plasmas

Catalogue Numbers: RSCN160 - Normal
RSCA170 - Abnormal

For *in vitro* diagnostic use only.

Intended Use
Reagent / System control (RSC) 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** 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
PT	PT
APTT	APTT

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

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

If both APTTs are out of range but 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
Reagent / System Control Plasma **50 vials**
Diagen RSC 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 1.5 mL of distilled water to the vial, mix gently and allow 5 - 10 for complete solution before use.

Warnings and precautions
POTENTIAL BIOHAZARD MATERIAL.
RSC 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:
Reagent / System Control Plasma.
Cat. No.
RSCN160 - Normal PT and APTT Control Plasma.
RSCA170 - 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 manufacturers 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 Reagent / System Control 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.

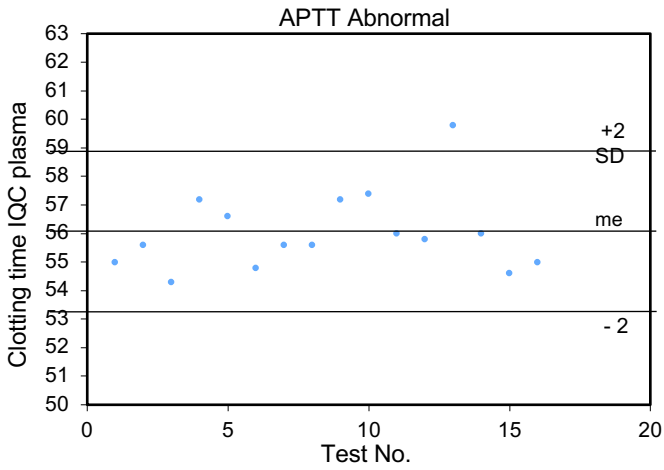

Figure 1. A Levey – Jennings Chart with two standard deviations either side of the mean clotting time.

Expected Results
Reagent / System Control Plasmas are manufactured to give PT & APTT values in the Normal range (RSCN160) & Abnormal Range (RSCA170) with Diagen PT & APTT reagents.

Limitations
Reagent / System Control 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 2 years at 4°C or below without deterioration. Once reconstituted the contents of the vial are then stable for up to 24 hours when held at 2 - 8°C and conform to a CV of <5.0%

Packaging
50 x 1.5 mL

Performance characteristics

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

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

Between run	PT	APTT
	CV%	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

REF Manufacturers catalogue number.

Consult instructions for use.

LOT Manufacturers batch number.

Recon. Requires reconstitution.

IVD For *in vitro* diagnostic use only.

Product expiry date.

Biological risks.

+4°C -20°C Store at 4°C or below. Best stored deep frozen.

Manufacturer.

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

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