Actalyke® QC Kit

CE

REF Cat. No. AQC–HP **IVD For In Vitro Diagnostic Use** **Store at 2-8°C**

Ranges / Bereiche / Intervalo de valores / Plages / Range / Amplitudes / Omfång

	Tube Type Röhrchen-Typ Tipo de Tubo Type d'éprouvette Tipo di provetta Tipo de tubo Rörtyp	Level and Range (seconds) Stufe und Bereich (Sekunden) Nivel e intervalo (segundos) Niveau et plage (en secondes) Livello e range (secondi) Nível e amplitude (segundos) Nivå och intervall (sekunder)	Level and Range (seconds) Stufe und Bereich (Sekunden) Nivel e intervalo (segundos) Niveau et plage (en secondes) Livello e range (secondi) Nível e amplitude (segundos) Nivå och intervall (sekunder)
AQC-HP	**C-ACT**	**Level I -**	**Level III -**
	K-ACT	**Level I -**	**Level III -**
	MAX-ACT®	**Level I -**	**Level III -**

LOT Kit Lot No. **Exp.**

LOT Vial Lot No. **Level I:** **Level III:**

H_2O: **$CaCl_2$:**

C-ACT, K-ACT and MAX-ACT ranges have been determined by assaying QC material on the Actalyke, Actalyke MINI and Actalyke XL Systems only.

Die Bereiche von C-ACT, K-ACT und MAX-ACT sind nur durch Testen von QC-Material an den Systemen Actalyke, Actalyke MINI und Actalyke XL bestimmt worden.

Los intervalos de valores de C-ACT, K-ACT y MAX-ACT han sido determinados únicamente por medio del análisis de material de QC con los Sistemas Actalyke, Actalyke MINI y Actalyke XL Systems.

Les gammes C-ACT, K-ACT et MAX-ACT ont été déterminées en dosant le matériel CQ sur les systèmes Actalyke, Actalyke MINI et Actalyke XL uniquement.

Il range C-ACT, K-ACT e MAX-ACT sono stati determinati saggiando il materiale QC soltanto sui sistemi Actalyke, Actalyke MINI e Actalyke XL.

As amplitudes de C-ACT, K-ACT e MAX-ACT foram determinadas através de ensaios de material de CQ apenas nos sistemas Actalyke, Actalyke MINI e Actalyke XL.

Intervallen för C-ACT, K-ACT och MAX-ACT har fastställts genom analys av kvalitetskontrollmaterial enbart på system Actalyke, Actalyke MINI och Actalyke XL.

INTENDED USE

The Actalyke QC Kit is a plasma control product intended for performing routine quality control testing of the Actalyke Activated Clotting Time test system. Two product configurations are available to meet different customer needs and to simulate different clinically significant ACT test results. Cat. No. AQC-HP contains Level I and Level III controls and is recommended for QC testing representative of normal and highly heparinized patient specimens (such as those undergoing cardiovascular procedures). Cat. No. AQC-LP contains Level I and Level II controls and is recommended for QC testing representative of normal and moderately heparinized patient specimens (such as those undergoing ECMO procedures or renal dialysis).

SUMMARY

Actalyke QC kits are recommended for the verification of proper test system performance combined with operator technique. In the US according to the CLIA '88 regulations, the frequency of quality control testing is mandated. Since the ACT is categorized as moderately complex, ACT users must (1) perform two levels of quality control during each shift in which the test system is used clinically, and (2) subscribe to a Proficiency Testing program. Additionally, CLIA (42 CFR 493) requires that biological controls be used weekly to verify system function. To help users comply with these regulations, Actalyke QC Kits are available.

Actalyke QC kits are manufactured using non-human plasma and provide results that are similar to those expected clinically, however some differences in values will be observed as compared to whole blood patient samples.

An expected range of values, appropriate to specific Actalyke test tubes, is published for each lot of Actalyke QC kits. This expected range facilitates the analysis of QC results obtained at a given institution, and enables the user to determine if his/her QC results are falling within "acceptable" limits. In addition, a "QC Management Chart" is provided in each Actalyke QC Kit to help users track their quality control test results.

PIPETTING OPTIONS

Syringes with needles or pipettes with plastic tips may be used for reconstitution and dispensing of reagents as follows.

A. SYRINGES WITH NEEDLES

Lift the seal tab to expose the stopper, leaving the outer ring of the seal in place. Puncture the stopper with the syringe needle, then aspirate or dispense the appropriate amount into each vial.

B. PIPETTES WITH PLASTIC TIPS

Remove the entire seal and the stopper from the vial. Pipette and dispense the appropriate volume into each vial.

REAGENTS

FOR IN-VITRO DIAGNOSTIC USE

1. Actalyke QC – Level I

Ingredients: The products contain citrated bovine plasma, rabbit brain extracts and buffers. Level I is a normal control for ACT systems.

Preparation for Use: Equilibrate all vials to room temperature before use. Add 1.0 mL of Reconstitution Water to the Actalyke control vial. Swirl gently to mix.

Allow the reconstituted control vial to stand for 5 minutes, swirling it gently at periodic intervals to assure complete reconstitution. At the end of 5 minutes, check material for complete dissolution. Allow to stand longer if not dissolved.

Storage and Stability: The controls should be stored at 2 to 8°C. The room temperature reconstituted product should be used within 1 hour. Unopened vials are stable until the expiration date marked on the vial.

2. Actalyke QC – Level III

Ingredients: The products contain citrated bovine plasma, rabbit brain extract, porcine heparin and buffers. Level III is highly elevated for higher clotting times.

Preparation for Use: Equilibrate all vials to room temperature before use. Add 1.0 mL of Reconstitution Water to the Actalyke control vial. Swirl gently to mix.

Allow the reconstituted control vial to stand for 5 minutes, swirling it gently at periodic intervals to assure complete reconstitution. At the end of 5 minutes, check material for complete dissolution. Allow to stand longer if not dissolved.

Storage and Stability: The controls should be stored at 2 to 8°C. The room temperature reconstituted product should be used within 1 hour. Unopened vials are stable until the expiration date marked on the vial.

3. Reconstitution Water

Ingredients: Deionized Water.

Preparation for Use: Ready for use as packaged.

Storage and Stability: Product should be stored at 2 to 8°C. Equilibrate to room temperature before use. Product is stable until the expiration date marked on the vial.

Sign of Deterioration: Discard if there is any cloudiness or evidence of contamination.

4. Calcium Chloride

Ingredients: 0.02 M calcium chloride.

Preparation for Use: Ready for use as packaged.

Storage and Stability: Product should be stored at 2 to 8°C. Equilibrate to room temperature before use. Product is stable until the expiration date marked on the vial.

Sign of Deterioration: Discard if there is any cloudiness or evidence of contamination.

PROCEDURE

Materials Supplied

Cat. No. AQC-HP (for use with MAX-ACT®, C-ACT, and K-ACT tubes)

- 10 X 1 mL Vials of Actalyke QC – Level I – Normal coagulation control.
- 10 X 1 mL Vials of Actalyke QC – Level III – Highly elevated coagulation control.
- 2 X 10 mL Vials Reconstitution Water – Distilled water.
- 2 X 10 mL Vials Calcium Chloride – 0.02 M calcium chloride.

Contains no human material.

Materials required, not supplied

- Actalyke, Actalyke MINI, or Actalyke XL instrument
- Actalyke ACT test tubes (MAX-ACT, C-ACT, or K-ACT tubes)
- 1.0 mL plastic syringes with needle
  or
- 1.0 mL plastic pipette tips

Step-By-Step

Note: Equilibrate all control, water and Calcium Chloride vials to room temperature prior to use.

1. Add the appropriate amount of Calcium Chloride given below into the appropriate ACT test tube. Mix well to assure complete dispersion of the activator.

C-ACT and K-ACT	1.0 mL $CaCl_2$
MAX-ACT	0.25 mL $CaCl_2$

2. Dispense the following amount of the reconstituted control into the ACT test tube containing Calcium Chloride.

C-ACT and K-ACT	1.0 mL Control
MAX-ACT	0.25 mL Control

3. Test the control in the same manner as the patient sample. Refer to the procedural insert packaged with the tubes for detailed instructions.

LIMITATIONS

Failure to obtain results that fall within the expected range of QC values may indicate product deterioration. Other factors that can also affect QC test results include technique and the temperature of the environment and materials used. If a QC test result falls outside the expected range, the test should be repeated using careful technique. If not, a study of each component of the system (i.e., Actalyke QC kit, Actalyke ACT test tube, and Actalyke instrument) should be performed so that the specific problem can be identified and corrected.

PERFORMANCE CHARACTERISTICS

Precision studies were done following NCCLS EP-5 guidelines to determine Within Run and Between Day precision. Between Day data represent duplicate determinations for twenty (20) days.

MAX-ACT

Level I	Within Run	Total Precision
Grand mean	176 sec.	176 sec.
SD	4.2	8.8
CV%	2.4	5.0
Level III	**Within Run**	**Total Precision**
Grand mean	356 sec.	356 sec.
SD	23.3	23.3
CV%	6.6	6.5

C-ACT

Level I	Within Run	Total Precision
Grand mean	174 sec.	174 sec.
SD	6.5	11.3
CV%	3.8	6.5
Level III	**Within Run**	**Total Precision**
Grand mean	278 sec.	278 sec.
SD	14.0	17.1
CV%	5.0	6.1

K-ACT

Level I	Within Run	Total Precision
Grand mean	173 sec.	173 sec.
SD	4.1	11.1
CV%	2.4	6.4
Level III	**Within Run**	**Total Precision**
Grand mean	288 sec.	288 sec.
SD	9.0	14.7
CV%	3.1	5.1

Level / Stufe / Nivel / Niveau / Livello / Nível / Nivå

Within Run / Innerhalb eines Laufs / Dentro de cada prueba / Intra-analyse / Entro la serie / Dentro da própria reacção / Inom körning

Total Precision / Präzision, gesamt / Precisión total / Précision totale / Precisione totale / Precisão total / Sammantagen precision

Grand mean / Gesamtmittelwert / Media grande / Moyenne totale / Media generale / Média geral / Totalmedelvärde

Sec. / s / s / s / sec. / seg. / sek.

SD (Standard Deviation) / Standardabweichung / Desviación Estándar / Ecarts-types / DS / Desvio padrão / Standardavvikelse

%CV (percentage coefficient of variation) / prozent variationskoeffizient / porcentaje coeficiente de variación / coefficient de variation / coefficiente di variazione in percentuale / coeficiente de percenta gem de variação / procentuell variationskoefficient

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