Introduction

The icIEF/CEInfinite Chemical Test Kit is designed to provide users with a convenient method of checking the daily performance of the icIEF/CEInfinite system utilizing the FC-coated cartridges. The kit is compatible with all commercial icIEF systems. The kit components include methylcellulose which is required for analysis using the FC-coated cartridge. The user should confirm proper operation of the icIEF/CEInfinite system if sample analysis results differ from what is expected.

By using this kit, the user is allowed to run a control test of the icIEF/CEInfinite system with the FC cartridge on 3 separate occasions. On each occasion, the user may check the system's performance repeatedly over a three-day period. At the end of the third day, the opened control samples and catholyte must be discarded.

This kit consists of anolyte, catholyte, 0.5% MC solution, IEF solution and a Hb stock with Hemoglobin A, F, S and C.

| Kit Contents | | | |
|---------------|---|----------|--|
| Solution # | Description | Qty/Amt | |
| 1 | Anolyte, 0.08M H₃PO₄ in 0.1% Methyl Cellulose | 10 mL | |
| 2 | Catholyte, 0.1% MC (NaOH introduced later) | 5 mL x 3 | |
| 3 | NaOH, 50% w/w | 500 μL | |
| 4 | 0.5% Methyl Cellulose (MC) | 10 mL | |
| 5 | Hemoglobin (Hb) Stock | 30 μL | |
| 6 | IEF Solution, 8% pH 3-10 AESlyte™ and two pI Markers (4.22, 9.46) in 0.35% MC | 1 mL x 3 | |
| 7 | Deionized water in 1.5 mL vials | 2 vials | |
| 8 | 0.5% MC Conditioning Solution in 1.5 mL | 1 vial | |

Preparation Procedure

Anolyte

Use Solution 1 (0.08M H_3PO_4 in 0.1% MC) as the anolyte (H+). Store at 2 $^{\circ}C$ to 8 $^{\circ}C$ after use.

Catholyte

Add 26 μ L of 50% NaOH (Solution 3) to Solution 2. Mark the label of Solution 2 using a marker after the NaOH is added. This mixture is used as the catholyte (OH-). It is stable for three days when stored at 2 °C to 8 °C.

Hemoglobin Control Solution

Add 5 μ L of Hb Stock (Solution 5) to the IEF Solution (Solution 6). Mark the label of the IEF Solution using a marker after the Hb Stock is added. This mixture is the Hemoglobin Control Solution. It is stable for three days when stored at 2 °C to 8 °C.

Set Focus Time

Two-stage focusing process is recommended, which will minimize spurious peaks and baseline noise:

| Focus Period | Voltage (V) | Time (mins) |
|--------------|-------------|-------------|
| 1 (Prefocus) | 1500 | 1.0 |
| 2 (Focus) | 3000 | 4.5 |

Kit Storage

Store at 2 °C to 8 °C.

Ordering Info

This kit can be ordered by:

· Phone: 1-519-653-6888

• Email: orders@aeslifesciences.com

• Online store: https://ceinfinite.com/registration/



Checking your Results

A typical electropherogram of the Hemoglobin Control Solution is shown in Figure 1. The sample contains two pl markers (pl 4.22 and pl 9.46) and four proteins. The four major protein peaks from left to right are: Hemoglobin A (HbA), HbF, HbS and HbC.

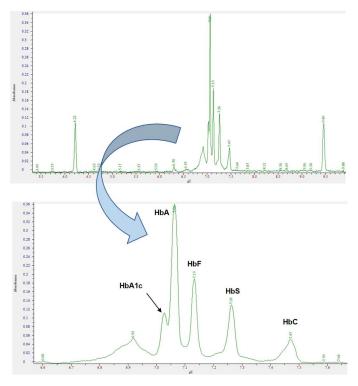


Figure 1. Typical Electropherogram for the Hemoglobin Control Solution.

Calibrate the x-axis of the electropherograms in your runs from position units (pixels) to pl units using icIEF/CEInfinite CFR Software. Table 1 shows the allowable results range when the icIEF system is working properly.

| Parameter | Allowable Range | |
|--|----------------------------|--|
| Overall pH range | 2 pl Marker peaks observed | |
| Resolution | HbA1c shoulder observed | |
| pl Accuracy | HbA pl value 7.00 ± 0.3 | |
| Peak Height (pl marker 9.46) | > 0.05 | |
| CV for 3 consecutive injections (pl marker 9.46) | ≤ 10% (peak height) | |

Table 1. Allowable result ranges.

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