



Medica Corporation
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Products For Health Care

Urine Diluent Stability Report

For pH Testing:

An EasyLyte Ca/pH Analyzer was qualified by performing two calibrations and analyzing Medica's EasyQC Level 2 (High Control Level) in duplicate. Results are deemed acceptable when meeting the specifications listed in the table below.

pH Specifications:

Calibration Range	QC Level 2 Ranges (Lot # 07351)
50 – 60	7.544 – 7.644

Three lots of Urine Diluent were tested in replicates of seven on the qualified EasyLyte Ca/pH analyzer. The lots that were tested and their age are listed in the table below.

Lot Number	Age (in months)
03204	53
04141	48
05054	35

The test urine diluent must meet the specifications listed in the table below.

EasyElectrolytes Urine Diluent pH Specifications	
%CV	Average Test Results
< 2.0%	7.71 – 7.83

The results from this study show that the urine diluent is stable at 53 months. This confirms the shelf life stability of 24 months for EasyElectrolytes Urine Diluent.

For the pH testing results, see Table # 1 below.



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For chloride (Cl-) testing:

An ISE Module was qualified by performing two calibrations and analyzing Medica's EasyQC Level 2 (High Control Level) in duplicate. Results are deemed acceptable when meeting the specifications listed in the table below.

Cl- Specifications:

Calibration Range	QC Level 2 Ranges (Lot # 07351)
45 – 60 mV	113 – 123 mmol/L

Three lots of Urine Diluent were tested in replicates of seven on the qualified ISE Module. The lots that were tested and their age are listed in the table below.

Lot Number	Age (in months)
03204	53
04141	48
05054	35

The test urine diluent must meet the specifications listed in the table below.

EasyElectrolytes Urine Diluent Cl- Specifications	
SD	Delta
< 5	-2 to 2

The results from this study show that the urine diluent is stable at 53 months. This confirms the shelf life stability of 24 months for EasyElectrolytes Urine Diluent.

For the chloride (Cl-) testing results, see Table # 2 below.

On Behalf of Medica Corporation

Stephanie Gorman
Regulatory Affairs Coordinator
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Table # 1: pH Testing Results:

Calibrations		
	pH	Pass/Fail
#1	54.86	Pass
#2	55.82	Pass

QC Level #2 - Lot # 07351		
	pH	Pass/Fail
#1	7.610	Pass
#2	7.615	Pass

Urine Diluent pH Testing			
Lot No.	03204	04141	05054
Age (Months)	53	48	35
#1	7.795	7.780	7.780
#2	7.795	7.780	7.795
#3	7.795	7.780	7.795
#4	7.790	7.780	7.795
#5	7.790	7.780	7.795
#6	7.795	7.795	7.795
#7	7.795	7.790	7.780
Mean:	7.794	7.784	7.791
SD:	0.002	0.006	0.007
%CV:	0.031	0.081	0.094
Pass/Fail	Pass	Pass	Pass



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Table # 2: Chloride (Cl-) Testing Results:

Calibrations		
	<u>Cl-</u>	<u>Pass/Fail</u>
#1	50.44	Pass
#2	50.70	Pass

QC Level # 2 - Lot # 07351		
	<u>Cl-</u>	<u>Pass/Fail</u>
#1	117.3	Pass
#2	117.6	Pass

Urine Diluent Cl- Testing			
Lot No.	03204	04141	05054
Age (Months)	53	48	35
#1	5.1	3.7	4.3
#2	4.3	4.8	5.4
#3	5.1	4.4	5.5
#4	4.7	5.1	4.7
#5	5.6	5.3	6.0
#6	4.4	4.4	5.1
#7	4.9	4.9	4.4
Mean:	4.9	4.7	5.1
SD:	0.45	0.54	0.62
Pass/Fail	Pass	Pass	Pass

Delta (Difference between lots)		
<u>Lot No.</u>	<u>Delta</u>	<u>Pass/Fail</u>
03204/04141	0.2	Pass
04141/05054	-0.4	Pass
05054/03204	0.2	Pass