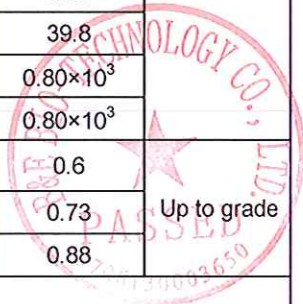




# CERTIFICATE OF ANALYSIS

Product	Calibration Pack for Electrolyte Analyzer	Lot. No.	X0078																				
Testing Date	2021.05.13	Model	CBS-300																				
Criterion	Operation Document of products Testing (ZYSW03-025)																						
Items	No.	Item Name	Requirement	Result	Conclusion																		
	1.1	Appearance	Transparent Liquid without Deposit	Transparent	Up to grade																		
	3	Package Sign	<p>the label of the electrolyte specific reagent package shall include at least the following:                      (a) Product name, model, specification;                      (b) main components, main uses;                      (c) Storage conditions;                      (d) production date, batch number and validity period;                      (e) the name and address of manufacturer, and contact information;</p> <p>the statement of use shall include at least the following:                      (a) Product name, packaging specification, intended use;                      (b) Storage conditions and validity period                      (c) sample requirements, testing methods and limitations of testing methods                      (d) performance requirements for reference ranges and products                      (e) the name and address of manufacturer.</p>	Up to grade	Up to grade																		
	1.2	Volume (ml)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">Standard A</td><td style="text-align: center;">530~540</td><td style="text-align: center;">531</td></tr> <tr><td style="text-align: center;">Standard B</td><td style="text-align: center;">210~220</td><td style="text-align: center;">212</td></tr> <tr><td style="text-align: center;">Standard C</td><td style="text-align: center;">220~230</td><td style="text-align: center;">222</td></tr> <tr><td style="text-align: center;">Solution Ref</td><td style="text-align: center;">310~320</td><td style="text-align: center;">310</td></tr> </table>	Standard A	530~540	531	Standard B	210~220	212	Standard C	220~230	222	Solution Ref	310~320	310	Up to grade							
	Standard A	530~540	531																				
	Standard B	210~220	212																				
	Standard C	220~230	222																				
	Solution Ref	310~320	310																				
	1.3	PH (25±1°C)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">Standard A</td><td style="text-align: center;">7.4±0.3</td><td style="text-align: center;">7.38</td></tr> <tr><td style="text-align: center;">Standard B</td><td style="text-align: center;">6.80±0.3</td><td style="text-align: center;">6.84</td></tr> <tr><td style="text-align: center;">Standard C</td><td style="text-align: center;">7.4±0.3</td><td style="text-align: center;">7.38</td></tr> <tr><td style="text-align: center;">Solution Ref</td><td style="text-align: center;">5.5±1.5</td><td style="text-align: center;">5.51</td></tr> </table>	Standard A	7.4±0.3	7.38	Standard B	6.80±0.3	6.84	Standard C	7.4±0.3	7.38	Solution Ref	5.5±1.5	5.51	Up to grade							
	Standard A	7.4±0.3	7.38																				
	Standard B	6.80±0.3	6.84																				
	Standard C	7.4±0.3	7.38																				
	Solution Ref	5.5±1.5	5.51																				
	1.4	Activity Concentration (mmol/L)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td rowspan="3" style="text-align: center;">Standard A</td><td style="text-align: center;">K<sup>+</sup> 4.0±0.4</td><td style="text-align: center;">3.90</td></tr> <tr><td style="text-align: center;">Na<sup>+</sup> 140.0±10</td><td style="text-align: center;">138.2</td></tr> <tr><td style="text-align: center;">Cl<sup>-</sup> 125.0±10</td><td style="text-align: center;">124.4</td></tr> <tr><td rowspan="3" style="text-align: center;">Standard B</td><td style="text-align: center;">K<sup>+</sup> 16.0±1.5</td><td style="text-align: center;">15.47</td></tr> <tr><td style="text-align: center;">Na<sup>+</sup> 35.0±10</td><td style="text-align: center;">34.5</td></tr> <tr><td style="text-align: center;">Cl<sup>-</sup> 41.0±10.0</td><td style="text-align: center;">39.8</td></tr> <tr><td rowspan="2" style="text-align: center;">Solution Ref</td><td style="text-align: center;">K<sup>+</sup> (0.80±0.15) ×10<sup>3</sup></td><td style="text-align: center;">0.80×10<sup>3</sup></td></tr> <tr><td style="text-align: center;">Cl<sup>-</sup> (0.80±0.15) ×10<sup>3</sup></td><td style="text-align: center;">0.80×10<sup>3</sup></td></tr> </table>	Standard A	K <sup>+</sup> 4.0±0.4	3.90	Na <sup>+</sup> 140.0±10	138.2	Cl <sup>-</sup> 125.0±10	124.4	Standard B	K <sup>+</sup> 16.0±1.5	15.47	Na <sup>+</sup> 35.0±10	34.5	Cl <sup>-</sup> 41.0±10.0	39.8	Solution Ref	K <sup>+</sup> (0.80±0.15) ×10 <sup>3</sup>	0.80×10 <sup>3</sup>	Cl <sup>-</sup> (0.80±0.15) ×10 <sup>3</sup>	0.80×10 <sup>3</sup>	Up to grade
	Standard A	K <sup>+</sup> 4.0±0.4	3.90																				
Na <sup>+</sup> 140.0±10		138.2																					
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	Na <sup>+</sup> 35.0±10	34.5																					
	Cl <sup>-</sup> 41.0±10.0	39.8																					
Solution Ref	K <sup>+</sup> (0.80±0.15) ×10 <sup>3</sup>	0.80×10 <sup>3</sup>																					
	Cl <sup>-</sup> (0.80±0.15) ×10 <sup>3</sup>	0.80×10 <sup>3</sup>																					
1.5.2	lot tolerance (R)%	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">K<sup>+</sup> ≤3.0</td><td style="text-align: center;">0.6</td></tr> <tr><td style="text-align: center;">Na<sup>+</sup> ≤3.0</td><td style="text-align: center;">0.73</td></tr> <tr><td style="text-align: center;">Cl<sup>-</sup> ≤3.0</td><td style="text-align: center;">0.88</td></tr> </table>	K <sup>+</sup> ≤3.0	0.6	Na <sup>+</sup> ≤3.0	0.73	Cl <sup>-</sup> ≤3.0	0.88	Up to grade														
K <sup>+</sup> ≤3.0	0.6																						
Na <sup>+</sup> ≤3.0	0.73																						
Cl <sup>-</sup> ≤3.0	0.88																						
Conclusion		Up to grade																					



Inspector: *Chunhong Shang*  
 Date: *2021.5.13*

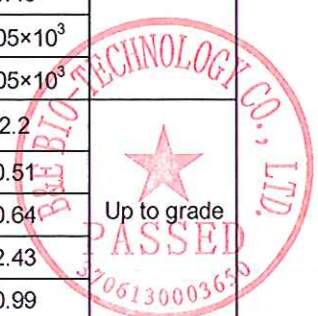
Reviewer: *Shuwei Liang*  
 Date: *2021.5.13*

Approver: *Xinlei Liu*  
 Date: *2021.5.13*



# CERTIFICATE OF ANALYSIS

Product	Calibration Pack for Electrolyte Analyzer	Lot. No.	X0079			
Testing Date	2021.06.28	Model	CBS-400			
Criterion	Operation Document of products Testing (ZYSW03-025)					
Items	No.	Item Name	Requirement	Result	Conclusion	
	1.1	Appearance	Transparent Liquid without Deposit	Transparent	Up to grade	
	3	Package Sign	<p>the label of the electrolyte specific reagent package shall include at least the following:</p> <p>(a) Product name, model, specification;</p> <p>(b) main components, main uses;</p> <p>(c) Storage conditions;</p> <p>(d) production date, batch number and validity period;</p> <p>(e) the name and address of manufacturer, and contact information;</p> <p>the statement of use shall include at least the following:</p> <p>(a) Product name, packaging specification, intended use;</p> <p>(b) Storage conditions and validity period</p> <p>(c) sample requirements, testing methods and limitations of testing methods</p> <p>(d) performance requirements for reference ranges and products</p> <p>(e) the name and address of manufacturer.</p>	Up to grade	Up to grade	
	1.2	Volume (ml)	Standard A	$\geq 530$	532	Up to grade
			Standard B	$\geq 210$	212	
			Standard C	$\geq 220$	222	
			Solution Ref	$\geq 310$	311	
	1.3	PH (25±1°C)	Standard A	7.4±0.3	7.38	Up to grade
			Standard B	6.8±0.3	6.84	
			Standard C	7.4±0.3	7.38	
			Solution Ref	5.5±1.5	5.51	
	1.4	Activity Concentration (mmol/L)	Standard A	K <sup>+</sup> 4.0±0.4	3.93	Up to grade
				Na <sup>+</sup> 140.0±10	139	
				Cl <sup>-</sup> 125.0±10	123.7	
				Ca <sup>2+</sup> 0.9±0.2	0.88	
			Standard B	K <sup>+</sup> 16.0±1.5	15.76	
				Na <sup>+</sup> 35.0±10	34	
				Cl <sup>-</sup> 41.0±10.0	40	
				Ca <sup>2+</sup> 1.5±0.3	1.46	
			Solution Ref	K <sup>+</sup> (0.80±0.15) ×10 <sup>3</sup>	0.805×10 <sup>3</sup>	
	Cl <sup>-</sup> (0.80±0.15) ×10 <sup>3</sup>			0.805×10 <sup>3</sup>		
1.5.2	lot tolerance (R)%	K <sup>+</sup> ≤3.0	2.2	Up to grade		
		Na <sup>+</sup> ≤3.0	0.51			
		Cl <sup>-</sup> ≤3.0	0.64			
		Ca <sup>2+</sup> ≤3.0	2.43			
		pH ≤3.0	0.99			
Conclusion		Up to grade				



Inspector: *Chunhong Shang*  
Date: *2021.6.28*

Reviewer: *Shuai Liang*  
Date: *2021.6.28*

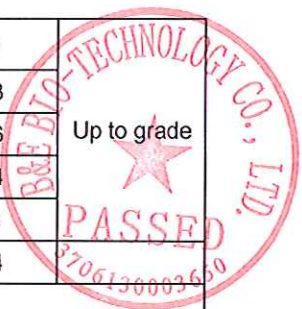
Approver: *Xinle Chen*  
Date: *2021.6.28*



## CERTIFICATE OF ANALYSIS

Product	Calibration Pack for Electrolyte Analyzer		Lot. No.	X0079		
Testing Date	2021.06.28		Model	CBS-500		
Criterion	Operation Document of products Testing (ZYSW03-025)					
No.	Item Name	Requirement		Result	Conclusion	
1.1	Appearance	Transparent Liquid without Deposit		Transparent	Up to grade	
3	Package Sign	the label of the electrolyte specific reagent package shall include at least the following: (a) Product name, model, specification; (b) main components, main uses; (c) Storage conditions; (d) production date, batch number and validity period; (e) the name and address of manufacturer, and contact information; the statement of use shall include at least the following: (a) Product name, packaging specification, intended use; (b) Storage conditions and validity period (c) sample requirements, testing methods and limitations of testing methods (d) performance requirements for reference ranges and products (e) the name and address of manufacturer.		Up to grade	Up to grade	
1.2	Volume (ml)	Standard A	$\geq 470$	532	Up to grade	
		Standard B	$\geq 180$	212		
		Standard C	$\geq 230$	222		
		Solution Ref	$\geq 260$	311		
		TCO <sub>2</sub> Calibrator Solution	$\geq 20$	22		
		Reaction Solution	$\geq 200$	202		
1.3	PH(25±1 °C)	Standard A	7.4±0.3	7.38	Up to grade	
		Standard B	6.8±0.3	6.84		
		Standard C	7.4±0.3	7.38		
		Solution Ref	5.5±1.5	5.51		
		TCO <sub>2</sub> Calibrator Solution	8.0±1.5	8.03		
		Reaction Solution	1.4±0.3	1.40		
1.4	Activity Concentration (mmol/L)	Standard A	K <sup>+</sup>	4.0±0.4	3.88	Up to grade
			Na <sup>+</sup>	140.0±10	138.8	
			Cl <sup>-</sup>	125.0±10	124.7	
			Ca <sup>2+</sup>	0.9±0.2	0.88	
		Standard B	K <sup>+</sup>	16.0±1.5	15.95	
			Na <sup>+</sup>	35.0±10	34.8	
			Cl <sup>-</sup>	41.0±10.0	40.3	
			Ca <sup>2+</sup>	1.5±0.3	1.47	
		Solution Ref	K <sup>+</sup>	(0.80±0.15) ×10 <sup>3</sup>	0.80×10 <sup>3</sup>	
			Cl <sup>-</sup>	(0.80±0.15) ×10 <sup>3</sup>	0.80×10 <sup>3</sup>	
TCO <sub>2</sub> Calibrator Solution	TCO <sub>2</sub>	30.0±5.0	30.38			

1.5.2	lot tolerance(R)%	$K^+ \leq 3.0$	0.6	Up to grade
		$Na^+ \leq 3.0$	0.73	
		$Cl^- \leq 3.0$	0.76	
		$Ca^{2+} \leq 3.0$	1.14	
		pH $\leq 3.0$	0.8	
		$TCO_2 \leq 6.0\%$	1.74	
Conclusion		Up to grade		



Inspector: *Chunhong Shang*  
Date: *2021.6.28*

Reviewer: *Shuair Liang*  
Date: *2021.6.28*

Approver: *Xinlei Cen*  
Date: *2021.6.28*