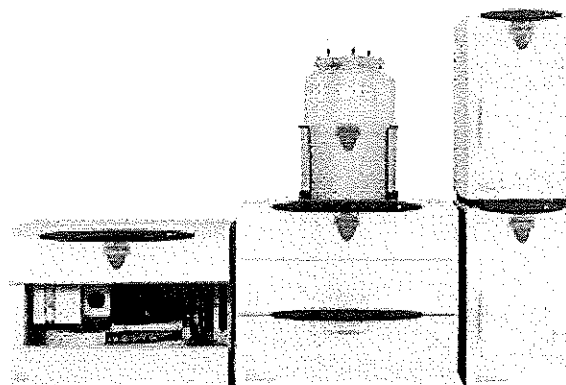




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REPORTE DE MANTENIMIENTO PREVENTIVO Y VERIFICACIÓN OPERACIONAL DEL SISTEMA CROMATOGRÁFICO IÓNICO



Información del cliente			
Compañía	SGS del Perú S.A.C - Laboratorio Medio Ambiente		
Dirección	Av Elmer Faucett 3348 , Callao		
Responsable	Frank Julcamoro	E-mail	Frank.Julcamoro@sgs.com
Teléfono	948435266	Código Equipo	MA-167-T
Fecha	18/1/2021	N° Ticket	ST2020-017
Sistema	ICS-5000	Responsable RPA	Freddy Bustamante

Información de los módulos instalados		
Módulo	Modelo	Número de serie
* Software de Control	Chromeleon	7.2
* Sistema Integrado ICS	No aplica	---
* Módulo de Bomba	ICS-5000 DP	11071122
* Módulo de Automuestreador	AS-AP	11071310
* Módulo de Detección	ICS-5000 DC	11071045
* Módulo de Eluyente	ICS-5000 EG	11071069
* Módulo Detector UV	No aplica	---
* Bomba Auxiliar	No aplica	---


Julio Hector
Ojeda Velarde

→ Av. Guardia Civil N° 657 - 661 / 6to. piso / San Borja

→ rpas@rpaperu.com

→ (511) 451 2457 / 452 0789 / 451 9648 / 561 0781

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REPORTE DE MANTENIMIENTO PREVENTIVO Y VERIFICACIÓN OPERACIONAL DEL SISTEMA CROMATOGRÁFICO IÓNICO

San Borja, Lunes, 18 de enero de 2021

Reporte N° ST2020-017

Señores:

SGS del Perú S.A.C - Laboratorio Medio Ambiente
Av Elmer Faucett 3348, Callao

Atención

Frank Julcamoro
Responsable

Referencia:

ENTREGA DEL REPORTE DE MANTENIMIENTO PREVENTIVO Y VERIFICACIÓN OPERACIONAL DEL SISTEMA
CROMATOGRÁFICO IÓNICO

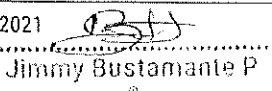
De nuestra consideración:

Haciendo extensivo nuestros saludos, nos es grato dirigirnos a Usted para informarle la realización del servicio realizado al sistema de Cromatografía Iónica de la marca Thermo Scientific, a efectos le remitimos lo siguiente:

RPA SAC, certifica la culminación del servicio realizado al cual se hace referencia en el encabezado de esta página

Objetivo del Servicio:

El objetivo del servicio realizado es asegurar, mediante las acciones realizadas, el correcto funcionamiento del equipo suministrado por nuestra representada, como sistema está sujeto a desgaste natural al ser operado y puede suceder que las especificaciones del proveedor ya no se cumplan. Por otro lado se verifica y confirma el completo suministro de los bienes entregados por RPA según requerimiento, propuesta, orden de compra o contrato.

Responsable RPA		Cliente (Usuario)	
Fecha:	18 de enero de 2021	Fecha:	18 de enero de 2021
Firma:	 Jimmy Bustamante P.	Firma:	
Nombre:	Freddy Bustamante	Nombre:	

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I.- Acciones Generales del Servicio:

Conforme No Conforme

1.- Verificación de voltaje de entrada al equipo

Valor medido

Línea - Neutro (220V +/- 10%)

220 V



Línea - Tierra (220V +/- 10%)

220 V



Neutro - Tierra (entre 0 y 1V)

0.1 V



2.- Protección Eléctrica del equipo instalado

El equipo utiliza Estabilizador

Si

El equipo utiliza UPS (Uninterruptible Power Supply)

Si

3.- Condiciones Ambientales

Valor medido

Temperatura: (Entre 14 y 40 °C, < 2.0 °C/Hora)

21.0 °C



Humedad Relativa: (entre 20 y 80 %, sin condensación)

45 %



II. Acciones realizadas previas al servicio del Equipo:

Conforme No Conforme

* Se realiza una inspección general para verificar el estado del sistema completo.



* Se enciende el equipo para verificar el self-test de inicialización de cada módulo.



* Se ingresa al software Chromeleon y se verifica la comunicación de cada módulo.



III.- Acciones Generales del Servicio:

Se realiza acciones de mantenimiento del sistema:

Conforme No Conforme

1.- Bomba del Equipo

Aplica ☒ No Aplica ☐

Se desensambla la bomba primaria y secundaria y se procede a limpiarlas.



Se realiza cambio de Kit de Mantenimiento



Se realiza la prueba de funcionamiento de ambos cabezales de bomba.



Se realiza el cambio de agua y se Purga la bomba.



Responsable RPA

Cliente (Usuario)

Fecha: 18 de enero de 2021

Fecha: 18 de enero de 2021

Firma:

Nombre: Freddy Bustamante

Jimmy Bustamante P.



Soporte
Técnico

Firma:

Nombre:

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			Conforme	No Conforme
2.- Valvula de Inyeccion	Aplica ☒	No Aplica ☐		
Se desensambla la valvula de inyeccion y se procede a limpiarlas.			☒	☐
Se realiza cambio de sellos y de ser necesario stator face.			☒	☐
Se realiza limpieza con agua de los canales del estator.			☒	☐
Se revisar que no existan fugas y se prueba su funcionamiento			☒	☐
3.- Compartimento de Columna	Aplica ☒	No Aplica ☐		
Se realiza limpieza del compartimiento.			☒	☐
Se evalua su funcionamiento a diferentes temperaturas..			☒	☐
Se realiza limpieza del intercambiador de calor.			☒	☐
4.- Detector del Cromatógrafo	Aplica ☒	No Aplica ☐		
Se realiza limpieza del detector.			☒	☐
Se estabiliza la linea base usando agua ultrapura.			☒	☐
5.- Generador de Eluyente	Aplica ☒	No Aplica ☐		
Se realiza limpieza del modulo Generador.			☒	☐
Se acondiciona y se conecta Test Box para pruebas de verificacion.			☒	☐
6.- Automuestreador del sistema	Aplica ☒	No Aplica ☐		
Se realiza limpieza del automuestreador.			☒	☐
Se realiza el cambio de Kit de mantenimiento			☒	☐
Se realiza la alineacion del automuestreador usando J-Clip.			☒	☐
Se realiza la calibracion TLV del equipo y se prueba.			☒	☐
Se configura el modulo para las pruebas de PQ.			☒	☐
7.- Detector VWD	Aplica ☐	No Aplica ☒		
Se realiza limpieza interna del modulo.			☐	☐
Se cambia lamparas de ser necesario.			☐	☐
Se estabiliza la linea base usando agua ultrapura.			☐	☐

Responsable RPA

Cliente (Usuario)

Fecha: 18 de enero de 2021

Fecha: 18 de enero de 2021

Firma: Jimmy Bustamante P

Firma:

Nombre: Freddy Bustamante

Nombre: Soporte Técnico

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→ rpaparu.com



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		Conforme	No Conforme
8.- Bomba Auxiliar	Aplica ☐ No Aplica ☒		
Se desensambla la bomba primaria y secundaria y se procede a limpiarlas.		☐	☐
Se realiza cambio de sellos, orings, y gaskets.		☐	☐
Se realiza el cambio de válvulas check.		☐	☐
Se revisa que no existan fugas y se prueba su funcionamiento		☐	☐
9.- Configuración para Pruebas PQ	Aplica ☒ No Aplica ☐		
Se realiza limpieza interna de los módulos del sistema.		☒	☐
Se puentean todos los consumibles del sistema.		☒	☐
Se acondiciona y se conecta tuberías y conexiones necesarias para las pruebas PQ.		☒	☐
Se prueba con un vial con agua las configuraciones del sistema para las pruebas PQ.		☒	☐

IV. Pruebas de Verificación Operacional

Aplica ☒ No Aplica ☐

1.- Se realiza una inspección general para verificar el estado en que se encuentra el instrumento

	Conforme	No Conforme
Se realiza una inspección general para verificar el estado en que se encuentra el sistema completo	☒	☐
Se enciende el equipo para verificar el self-test de inicialización	☒	☐
Se ingresa al software Chromeleon y se verifica la comunicación entre el instrumento y el software	☒	☐
Se verifica el Performance de la línea base pasando agua como eluyente	☒	☐
Se cargan las pruebas de Calificación de Desempeño (PQ)	☒	☐
Se configura el instrumento para pruebas de PQ	☒	☐
Se monitorea la presión del sistema y se evalúa su estabilidad	☒	☐
Se realizan las pruebas de Calificación de Desempeño	☒	☐

	Conforme	No Conforme
2.- Explicación de las pruebas de PQ del sistema Cromatógrafo Iónico		
2.1.- Warm Up	☒	☐
Es una secuencia usada para asegurar que todas las partes del sistema se encuentra respondiendo apropiadamente y sean registradas en el log book del sistema (luego usado para actualizar la información en el file del reporte).		

Responsable RPA

Cliente (Usuario)

Fecha: 18 de enero de 2021

Fecha: 18 de enero de 2021

Firma:

Jimmy Bustamante P.

Firma:

Nombre: Freddy Bustamante

Soporte Técnico

Nombre:

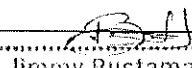
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				Conforme	No Conforme
2.2.-Detector Noise and Drift	Aplica	☒	No Aplica	☐	☒
Se realiza solo usando el agua como eluyente a un flujo de 1.0 ml/min. El ruido es calculado dividiendo la señal de línea base valuado en 20 minutos en intervalos de 1 minuto. Este ruido es la distancia promedio entre líneas paralelas de medidas de valores máximos y mínimos y la regresión lineal. Para calcular el Drift (Deriva), el software Chromeleon usa el método de mínimos cuadrados y calcula la regresión lineal de valores medidos. La pendiente de la curva indica la deriva de la señal medida y la cantidad de la pendiente indica la cantidad de deriva.					
2.3.-Injector Linearity	Aplica	☒	No Aplica	☐	☒
La precisión de la inyección es determinada realizando réplicas de inyecciones de un estándar usando un volumen de muestra variable de 10, 20, 30, 40 y 50 uL. Un estándar de 50 ppm de Nitrato es inyectado y agua es usado como eluyente a un flujo de 1.0 ml/min.					
2.4.- Sample Carry-Over	Aplica	☒	No Aplica	☐	☒
En la evaluación del Carry Over el área de un pico es calculado para determinar la muestra carry-over (arrastre o contaminación cruzada). Se usa 1000 ppm de Nitrato como Estándar alto y agua como muestra de acarreo, se usa otra muestra de agua como referencia.					
2.5.- Detector Linearity	Aplica	☒	No Aplica	☐	☒
La linealidad del Detector para detectores de conductividad usa una secuencia de 5 inyecciones de un estándar de nitrato de 5, 10, 25, 50 y 100 ppm. Agua es usado como eluyente a un flujo de 1.0 ml/min.					
2.6.- Injector Precisión	Aplica	☒	No Aplica	☐	☒
La precisión de la inyección es determinada realizando réplicas de 10 inyecciones de un estándar usando un volumen de muestra fijo. Un estándar de 50 ppm de Nitrato es inyectado y agua es utilizado como eluyente a un flujo de 1.0 ml/min.					
2.7.- Column Heater Temperature	Aplica	☒	No Aplica	☐	☒
La temperatura del compartimiento de detector y de la Columna es calificado midiendo las temperaturas después de haber equilibrado la temperatura por lo menos 15 minutos. La temperatura es medida con un termómetro calibrado y comparado con la temperatura que se muestra en el software Chromeleon. Durante la secuencia la temperatura del compartimiento es configurada a 20°C, y la temperatura de columna a 30°C.					

Responsable RPA		Cliente (Usuario)	
Fecha:	18 de enero de 2021	Fecha:	18 de enero de 2021
Firma:		Firma:	
Nombre:	Freddy Bustamante	Nombre:	

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				Conforme	No Conforme
2.8.- EG Current Test	Aplica	☒	No Aplica	☐	☒
Se utiliza agua como eluyente, se conecta el IC Qualification Test Box para medir las corrientes que entrega el módulo EG al cartucho. Se usa un Multímetro Digital calibrado para medir las corrientes del EG.					
2.9.- Gradient Pump Accuracy	Aplica	☒	No Aplica	☐	☒
Se utiliza ambos eluentes agua y KCl para combinarlos en diferentes porcentajes y reportar el estado de las válvulas gradientes del sistema.					
2.10.- Exactitud de longitud de onda VWD	Aplica	☐	No Aplica	☒	☐
Se realiza la prueba de longitud en 360.9nm, 418nm, 536.6nm usando agua como Eluyente.					
2.11.- VWD Detector Linearity	Aplica	☐	No Aplica	☒	☐
La linealidad del Detector para detectores UV usa una secuencia de 5 inyecciones de un estándar de cafeína de 15, 40, 60, 80 y 100ppm.					

Responsable RPA

Fecha: 18 de enero de 2021

Jimmy Bustamante P.

Firma:

Nombre: Freddy Bustamante

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Cliente (Usuario)

Fecha: 18 de enero de 2021

Firma:

Nombre:

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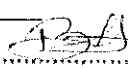
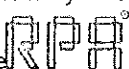
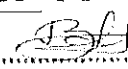
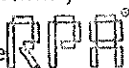
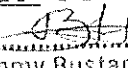
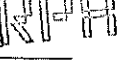
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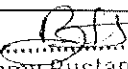
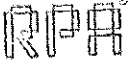
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V.- Conclusiones:

Equipo Operativo y Verificado

VI.- Comentarios u Observaciones del Servicio:

Sección	Comentario	Operador
I	Sin comentarios	Fecha: 18 de enero de 2021  Jimmy Bustamante P Firma:  Soporte Nombre: Freddy Bustamante Técnico
II	Sin comentarios	Fecha: 18 de enero de 2021  Jimmy Bustamante P Firma:  Soporte Nombre: Freddy Bustamante Técnico
III	Sin comentarios	Fecha: 18 de enero de 2021  Jimmy Bustamante P Firma:  Soporte Nombre: Freddy Bustamante Técnico
IV	Sin comentarios	Fecha: 18 de enero de 2021  Jimmy Bustamante P Firma:  Soporte Nombre: Freddy Bustamante Técnico

Responsable RPA	Cliente (Usuario)
Fecha: 18 de enero de 2021  Jimmy Bustamante P Firma:  Soporte Nombre: Freddy Bustamante Técnico	Fecha: 18 de enero de 2021 Firma: Nombre:

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CERTIFICADO DE VERIFICACIÓN OPERACIONAL

Declaración obtenida del resultado de la Verificación Operacional del sistema de Cromatografía Iónica

Compañía: SGS del Perú S.A.C - Laboratorio Medio Ambiente

Equipo: ICS-5000

Marca: Thermo Scientific

Código de ICS: MA-167-T

I. DESCRIPCIÓN DEL EQUIPO INSTALADO

Información de los módulos instalados		
Módulo	Modelo	Número de serie
* Software de Control	Chromeleon	7.2
* Sistema Integrado ICS	No aplica	---
* Módulo de Bomba	ICS-5000 DP	11071122
* Módulo de Automuestreador	AS-AP	11071310
* Módulo de Detección	ICS-5000 DC	11071045
* Módulo de Eluyente	ICS-5000 EG	11071069
* Módulo Detector UV	No aplica	---
* Bomba Auxiliar	No aplica	---

II. CONCLUSIONES Y COMENTARIOS

* El equipo: ICS-5000

De la marca Thermo Scientific, cumplió con la verificación Operacional

* Las pruebas realizadas a cada módulo del equipo se adjuntan como anexo a este reporte de servicio.

Fecha de Verificación Operacional : lunes, 18 de enero de 2021

Próxima Verificación Operacional (o después de una reparación mayor) : martes, 18 de enero de 2022

Responsable RPA : Freddy Bustamante



Jimmy Bustamante P.
RPA® Soporte
Técnico

Pruebas de Verificacion Operacional realizadas en el Sistema 1



Performance Qualification Rev. 7.30 for Chromeleon 7.2

• Instruments

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1. 1. 0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1. 1. 0
Fluorescence Detector	n.a.	Thermo Fisher	n.a.	n.a.
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0
Eluent Generator	ICS-5000(+) EG (EGC KOH)	Thermo Fisher	11071069	1. 0. 0
Chromatography Datasystem	7.2.10.23925	Thermo Fisher	2197	n.a.

• Accessories

Name	Description	Vendor	Lot / Serial	Exp. Date
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")			
Blank	Water			
ECD Sample 1	Nitrate, 5 ppm		201006	oct-21
ECD Sample 2	Nitrate, 10 ppm		201006	oct-21
ECD Sample 3	Nitrate, 25 ppm		201006	oct-21
ECD Sample 4	Nitrate, 50 ppm		201006	oct-21
ECD Sample 5	Nitrate, 100 ppm		201006	oct-21
ECD Sample 6	Nitrate, 1000 ppm		201006	oct-21
Eluent A and C	Water			
Eluent B and D	1.0 mM KCl			
Autosampler Reservoir A	Water			
Balance				
Temperature Probe	Fluke 179		19320093	jun-21
IC Qualification Test Box	Test Box II		18020705	feb-22
Ammeter / Multimeter	Fluke 179		19320093	jun-21
ED/CD Validation Test Cell				

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Custamante P.
RPA Soporte Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Specification
Printed: 20/1/2021 2:20 p. m.

• Limits

Test	Customized Limits	Dionex Recommended Limits
Conductivity Noise (nS)	≤ 2.0	≤ 2.0
Conductivity Drift (nS/hr)	≤ 20	≤ 20
Injector Precision (Area %RSD)	≤ 1.0	≤ 1.0
Injector Carryover (Area %)	≤ 0.1	≤ 0.1
Conductivity Linearity (Corr.)	≥ 0.999	≥ 0.999
Conductivity Linearity (%RSD)	≤ 5.0	≤ 5.0
Injector Linearity (Corr.)	≥ 0.999	≥ 0.999
Injector Linearity (%RSD)	≤ 1.0	≤ 1.0
Eluent Generator Step Current (mA)	See Worksheet(s)	See Worksheet(s)
Pump Gradient Accuracy (%)	≤ 2.0	≤ 2.0
Pump Noise (%)	$\leq 0.2\%$	$\leq 0.2\%$
Pump Flow Accuracy (mL/min)	≤ 0.05	≤ 0.05
Pump Flow Precision (%RSD)	$\leq 2.0\%$	$\leq 2.0\%$
Heater Temperature Verification	≤ 2.5	≤ 2.5

• Additional Information

Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

Dionex

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante : P
RPA Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Specification
Printed: 20/1/2021 2:20 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Injector Carryover:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1.1.0
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 6	Nitrate, 1000 ppm		201006
Blank	Water		
Eluent A and C	Water		

• Additional Information

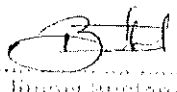
Customer/Company:	SGS del Peru	Date:	14-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period Between Qualification:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Injector Carryover (Area %)	PASS

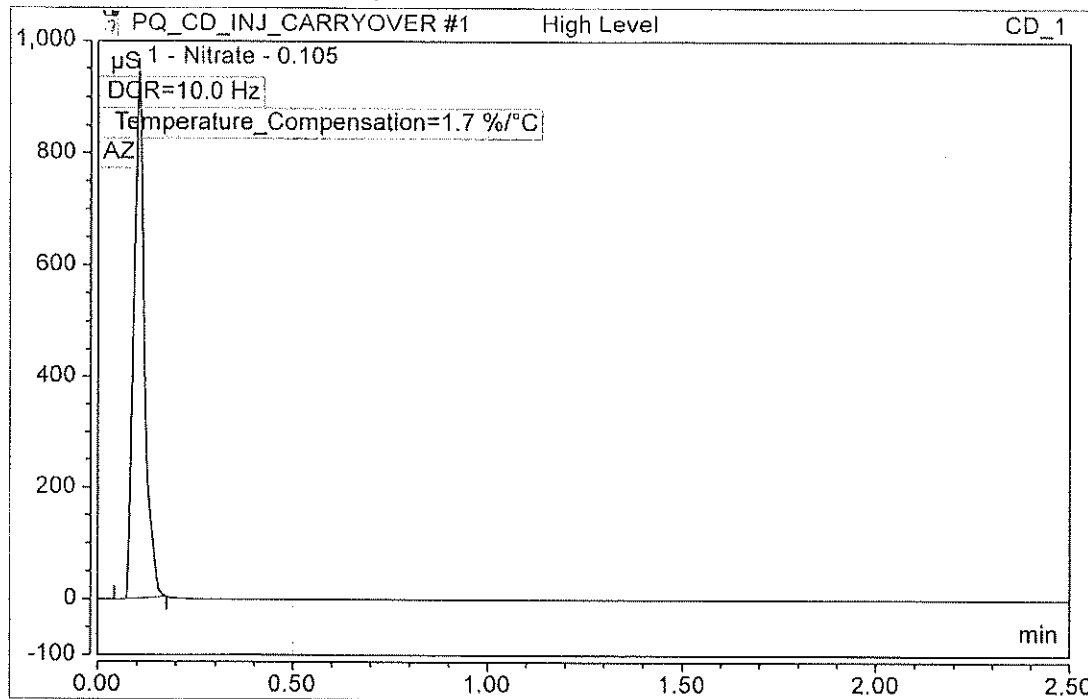
Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante / P
RPA Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Carry_Over
Printed: 20/1/2021 2:25 p. m.

• **Chromatogram for Carryover Test**

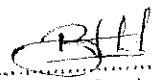


• **Data for Carryover Test**

Name	Ret.Time (detected) min	Area $\mu S \cdot min$
	CD_1	CD_1
	Nitrate	Nitrate
High Level	0.11	29.417
Carryover	0.10	0.027
Water	0.10	0.015
Carryover: (%)		0.0
Limit: (%)		0.1
Result:		PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P.
RPA Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Carry_Over
Printed: 20/1/2021 2:25 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Detector Linearity:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1. 1. 0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1. 1. 0
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 1	Nitrate, 5 ppm		201006
ECD Sample 2	Nitrate, 10 ppm		201006
ECD Sample 3	Nitrate, 25 ppm		201006
ECD Sample 4	Nitrate, 50 ppm		201006
ECD Sample 5	Nitrate, 100 ppm		201006
Eluent A and C	Water		

• Additional Information

Customer/Company:	SGS del Peru	Date:	14-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Conductivity Linearity (Corr.)	PASS
Conductivity Linearity (%RSD)	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Bustamante P
RPA Soporte
Técnico

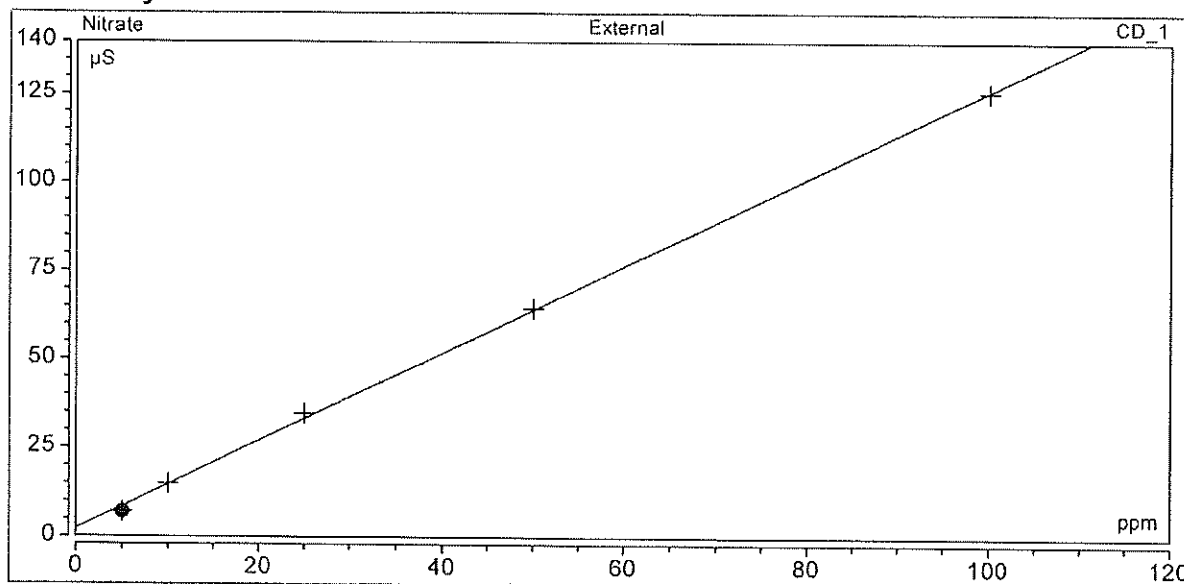
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Det_Linearity
Printed: 20/1/2021 2:28 p. m.

• Data for Detector Linearity

Sample Name	Amount n.a.	Height μ S CD_1 Nitrate	Residual CD_1 Nitrate
Detector linearity_1	5.0000	7.1432	-1.3936
Detector linearity_2	10.0000	14.9091	0.1789
Detector linearity_3	25.0000	34.6416	1.3309
Detector linearity_4	50.0000	64.6076	0.3294
Detector linearity_5	100.0000	125.7675	-0.4456
Variance			1.351
Standard Deviation			1.162

• Linearity Plot

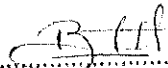


Cal. Type	Number of Points	Offset	Slope
Lin, WithOffset	5	2.343	1.239

	Correlation Coefficient	% RSD
Linearity	1.000	2.4
Limit:	0.999	5.0
Result:	PASS	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
Soporte Técnico
RPA

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Det_Linearity
Printed: 20/1/2021 2:28 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

EG Current Test:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Eluent Generator	ICS-5000(+) EG (EGC KOH)	Thermo Fisher	11071069	1. 0. 0

• Accessories

Name	Description	Vendor	Lot / Serial
IC Qualification Test Box	Test Box II		18020705
Ammeter / Multimeter	Fluke 179		19320093

• Additional Information

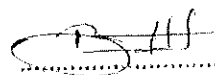
Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Cartridge Position	Cartridge Type	Result
EGC Current	EGC_1	EGC KOH	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
RPA Soporte Técnico
Executor Signature _____ Date _____

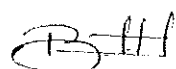
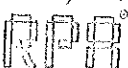
OQ_PQ_Modular_Validation / EG_Current
Printed: 20/1/2021 2:32 p. m.

• Data for ICS-5000(+) EG (EGC KOH) Current Qualification Test

Concentration (mM)	Theoretical Current (mA)	Measured Current (mA)	Limit (+/-)	Deviation	Result
	0.00	0.00	1.00	0.00	PASS
	3.22	3.22	1.00	0.00	PASS
	4.82	4.82	1.00	0.00	PASS
	6.43	6.43	1.20	0.00	PASS
	8.04	8.04	1.40	0.00	PASS
	16.08	16.08	2.00	0.00	PASS
	24.12	24.12	2.00	0.00	PASS
	32.16	32.16	2.60	0.00	PASS
	40.20	40.20	3.20	0.00	PASS
	48.24	48.24	3.80	0.00	PASS
	56.28	56.28	4.60	0.00	PASS
	64.32	64.32	5.20	0.00	PASS
	80.40	80.40	6.40	0.00	PASS
	96.49	96.49	7.60	0.00	PASS
	128.65	128.65	10.40	0.00	PASS
	160.81	160.81	12.80	0.00	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / EG_Current
Printed: 20/1/2021 2:32 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Pump Flow Rate Accuracy and Precision Test:

• Instruments and Fluidics

Analytical Mode

Instrument Name	Model	Supplier	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Chromeleon	7.2.10.23925	Thermo Fisher	2197	n.a.

• Accessories:

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
Balance			

• Limits:

Test	Customized Limits	Thermo Fisher Rec. Limits
Pump Flow Accuracy (mL/min)	0.05	0.05
Pump Flow Precision (%RSD)	<= 2.0	<= 2.0

• Additional Information:

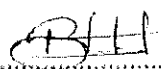
Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification	Jimmy Bustamante/RPA	Period between Qualifications:	12 months
Executor/Company:		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Pump Flow Accuracy (mL/min)	PASS
Pump Flow Precision (%RSD)	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
Soporte Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Flow_Rate
Printed: 20/1/2021 2:23 p. m.

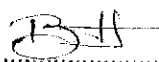
• **Data for Pump Flow Rate Accuracy and Precision Test**

Temperature (°C)	21
------------------	----

Segment	Measured Eluent Weight (g)	Calculated Eluent Flow Rate (mL/min)	Deviation from 1.00 mL/min	Limit	Result
0	15.987	-	-	-	-
1	20.979	1.000	0.000	0.05	PASS
2	25.968	1.000	0.000	0.05	PASS
3	30.955	0.999	0.001	0.05	PASS
4	35.941	0.999	0.001	0.05	PASS
5	40.933	1.000	0.000	0.05	PASS
Average		1.000		Overall	PASS
Standard Deviation		0.001			
% RSD		0.1			

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnica
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Flow_Rate
Printed: 20/1/2021 2:23 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Gradient Pump Accuracy and Noise:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1. 1. 0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
Eluent A and C	Water		
Eluent B and D	1 mM KCl		

• Additional Information

Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification	Jimmy Bustamante/RPA	Period Between Qualifications:	12 months
Executor/Company:		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Step Accuracy - A, B	PASS
Step Accuracy - C, D	PASS
Step Noise - A, B	PASS
Step Noise - C, D	PASS

Customer Signature _____ Date _____

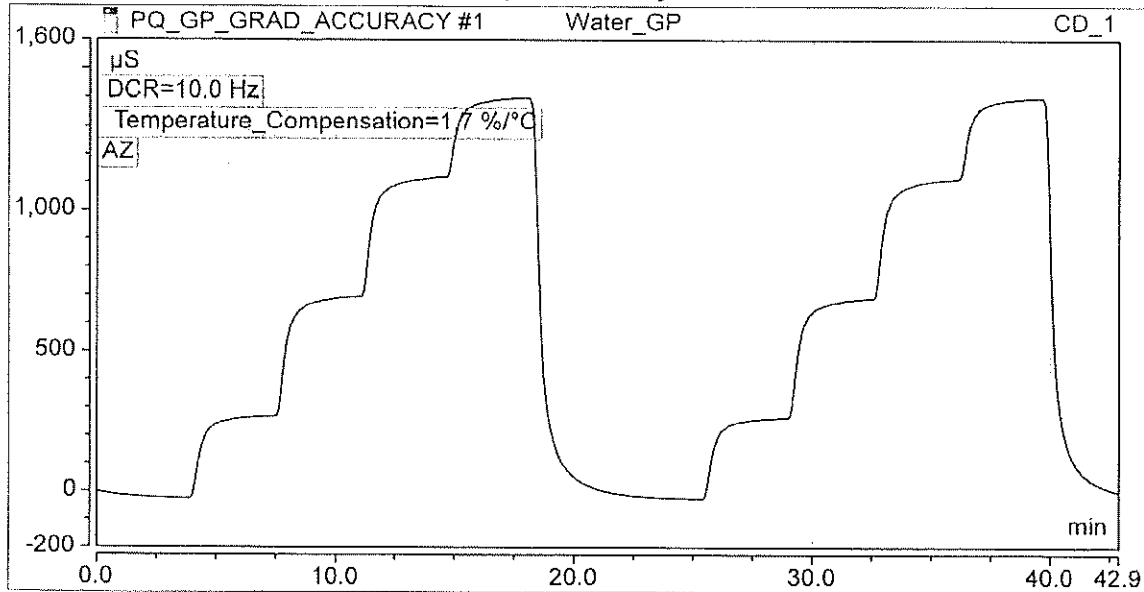
Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Bustamante P

Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Gradient_Accuracy
Printed: 20/1/2021 2:35 p. m.

• **Chromatogram of Gradient Pump Accuracy**



• **Step Accuracy - Valves A, B**

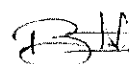
Theoretical Value (%)	Conductivity (µS)	Calculated Value (%)	Deviation (%)	Limit (+/-, %)	Result
0.00	-23.71	0.00	0.00	N/A	----
20.00	272.39	20.82	0.82	2.0	PASS
50.00	701.75	51.00	1.00	2.0	PASS
80.00	1125.04	80.75	0.75	2.0	PASS
100.00	1398.82	100.00	0.00	2.0	PASS

• **Step Accuracy - Valves C, D**

Theoretical Value (%)	Conductivity (µS)	Calculated Value (%)	Deviation (%)	Limit (+/-, %)	Result
0.00	-24.01	0.00	0.00	N/A	----
20.00	267.68	20.52	0.52	2.0	PASS
50.00	689.35	50.19	0.19	2.0	PASS
80.00	1112.19	79.94	-0.06	2.0	PASS
100.00	1397.23	100.00	0.00	2.0	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
RPA Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Gradient_Accuracy
Printed: 20/1/2021 2.35 p. m.

• **Step Noise - Valves A, B**

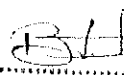
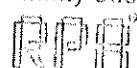
Step (%)	Noise (μ S)	Calculated Noise (%FS)	Limit (%)	Result
0.00	0.27	0.02%	0.20%	PASS
20.00	0.13	0.01%	0.20%	PASS
50.00	0.98	0.07%	0.20%	PASS
80.00	0.15	0.01%	0.20%	PASS
100.00	0.51	0.04%	0.20%	PASS

• **Step Noise - Valves C, D**

Step (%)	Noise (μ S)	Calculated Noise (%FS)	Limit (%)	Result
0.00	0.72	0.05%	0.20%	PASS
20.00	0.89	0.06%	0.20%	PASS
50.00	0.34	0.02%	0.20%	PASS
80.00	0.43	0.03%	0.20%	PASS
100.00	0.61	0.04%	0.20%	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Gradient_Accuracy
Printed: 20/1/2021 2:35 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Injector Linearity:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1. 1. 0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1. 1. 0
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 4	Nitrate, 50 ppm		201006
Eluent A and C	Water		

• Additional Information

Customer/Company:	SGS del Peru	Date:	14-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Injector Linearity (Corr.)	PASS
Injector Linearity (%RSD)	PASS

Customer Signature _____ Date _____

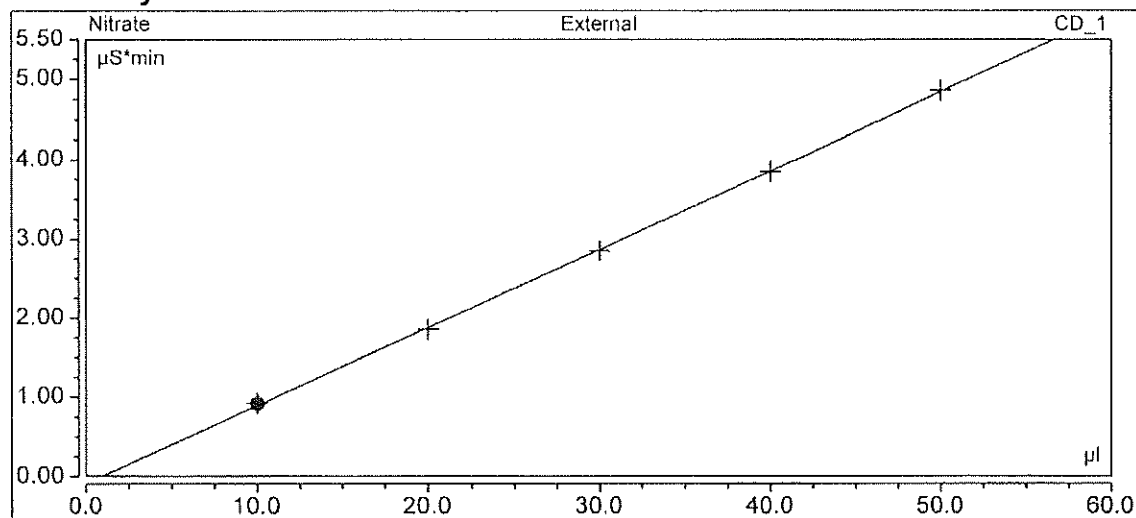
Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Bustamante P
RPA Soporte Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Inj_Linearity
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• **Linearity Plot**



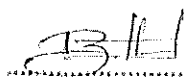
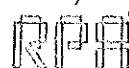
• **Data for Injector Linearity Test**

Name	Ret. Time (detected) min CD_1 Nitrate	Inj. Vol. µL	Area µS*min CD_1 Nitrate	Residuals CD_1 Nitrate
Injector Linearity_1	0.10	10.0	0.924	0.0274
Injector Linearity_2	0.10	20.0	1.859	-0.0243
Injector Linearity_3	0.10	30.0	2.854	-0.0154
Injector Linearity_4	0.11	40.0	3.851	-0.0058
Injector Linearity_5	0.10	50.0	4.861	0.0181
Variance				0.0006
Standard Deviation				0.0254

Cal. Type	Number of Points	Offset	Slope
Lin, WithOffset	5	-0.091	0.099

	Correlation Coefficient	% RSD
Injector Linearity	1.000	0.9
Limit:	0.999	1.0
Result:	PASS	PASS

Customer Signature _____ Date _____


Jimmy Bustamante P.
 Soporte
Técnico
Executor Signature _____ Date _____



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Injector Precision:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1.1.0
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 4	Nitrate, 50 ppm		201006
Eluent A and C	Water		

• Additional Information

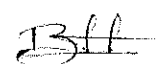
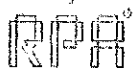
Customer/Company:	SGS del Peru	Date:	14-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period Between Qualification	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Injector Precision (Area %RSD)	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico
Executor Signature _____ Date _____

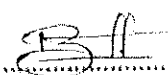
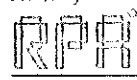
OQ_PQ_Modular_Validation / Inj_Precision
Printed: 20/1/2021 2:27 p. m.

• **Data for Injector Precision Test**

	<i>Injector Precision</i>
<i>Name</i>	<i>Area</i> <i>μS*min</i> <i>CD_1</i> <i>Nitrate</i>
Inj Precision_1	2.095
Inj Precision_2	2.090
Inj Precision_3	2.084
Inj Precision_4	2.092
Inj Precision_5	2.082
Inj Precision_6	2.083
Inj Precision_7	2.085
Inj Precision_8	2.096
Inj Precision_9	2.095
Inj Precision_10	2.098
Average:	2.090
Std Dev:	0.006
% RSD:	0.3
Limit:	1.0
Result:	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Inj_Precision
Printed: 20/1/2021 2:27 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Conductivity Detector Noise and Drift:

• Instruments and Fluidics Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Gradient)	Thermo Fisher	11071122	6.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1. 1. 0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
Eluent	Water		

• Additional Information

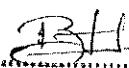
Customer/Company:	SGS del Peru	Date:	14-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period Between Qualification	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Noise	PASS
Drift	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
RPA Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Noise_and_Drift
Printed: 20/1/2021 2:29 p. m.

• **Data for Detector Noise**

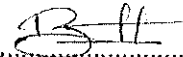
Segment No.	Noise, nS
1	0.41
2	0.30
3	0.40
4	0.32
5	0.41
6	0.29
7	0.29
8	0.29
9	0.31
10	0.40
11	0.28
12	0.29
13	0.32
14	0.39
15	0.48
16	0.28
17	0.74
18	0.30
19	0.33
20	0.30
Average, nS	0.4
Limit, nS	2.0
Result	PASS

• **Data for Detector Drift**

20 Minute Drift, nS	Drift, nS/hr	Limit, nS/hr	Result
2.2	6.6	20.0	PASS

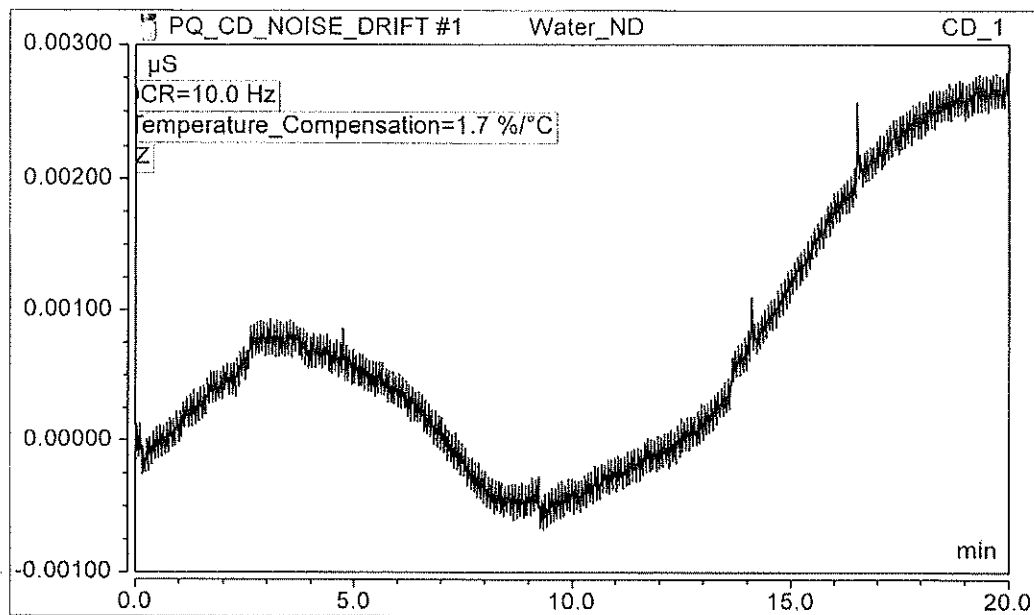
Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Noise_and_Drift
Printed: 20/1/2021 2:29 p. m.

• *Chromatogram of Detector Noise and Drift*



Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P.
 Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Noise_and_Drift
Printed: 20/1/2021 2:29 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Column Heater Temperature Verification:

• Instruments

Analytical Mode

Instrument Name	Model	Supplier	Serial Number	Moduleware Version
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1. 1. 0
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14052472	1. 1. 0

• Accessories

Name	Description	Vendor	Lot / Serial
Temperature Probe	Fluke 179		19320093

• Additional Information

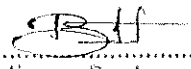
Customer/Company:	SGS del Peru	Date:	14-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante/RPA	Period Between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Heater Temperature Verification	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
RPA Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Temperature
Printed: 20/1/2021 3:42 p. m.

• **Data for Column Heater Temperature**

<i>Measured Column Temperature (°C)</i>	30.30
<i>Measured Compartment Temperature (°C)</i>	20.10

	<i>Theoretical Temp (°C)</i>	<i>Difference (°C)</i>	<i>Limit (+/-)</i>	<i>Result</i>
<i>Column Heater Temperature (°C)</i>	30.00	-0.30	<= 2.5	PASS
<i>Compartment Heater Temperature (°C)</i>	20.00	-0.10	<= 2.5	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P

 Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Temperature
Printed: 20/1/2021 3:42 p. m.

Pruebas de Verificacion Operacional realizadas en el Sistema 2



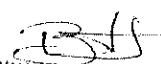
Performance Qualification Rev. 7.30 for Chromeleon 7.2

• Instruments

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Isocratic)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14061177	1.1.0
Fluorescence Detector	n.a.	Thermo Fisher	n.a.	n.a.
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0
Eluent Generator	ICS-5000(+) EG (EGC K2CO3)	Thermo Fisher	11071069	1.0.0
Chromatography Datasystem	7.2.10.23925	Thermo Fisher	2197	n.a.

• Accessories

Name	Description	Vendor	Lot / Serial	Exp. Date
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")			
Blank	Water			
ECD Sample 1	Nitrate, 5 ppm		201006	oct-21
ECD Sample 2	Nitrate, 10 ppm		201006	oct-21
ECD Sample 3	Nitrate, 25 ppm		201006	oct-21
ECD Sample 4	Nitrate, 50 ppm		201006	oct-21
ECD Sample 5	Nitrate, 100 ppm		201006	oct-21
ECD Sample 6	Nitrate, 1000 ppm		201006	oct-21
Eluent A	Water			
Autosampler Reservoir A	Water			
Balance				
Temperature Probe	Fluke 179		19320093	jun-21
IC Qualification Test Box	Test Box II		18020705	feb-22
Ammeter / Multimeter	Fluke 179		19320093	jun-21
ED/CD Validation Test Cell				


Jimmy Bustamante P.
RPA Soporte Técnico
Executor Signature

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925

OQ_PQ_Modular_Validation / Specification
Printed: 20/1/2021 2:45 p. m.

• Limits

Test	Customized Limits	Dionex Recommended Limits
Conductivity Noise (nS)	<= 2.0	<= 2.0
Conductivity Drift (nS/hr)	<= 20	<= 20
Injector Precision (Area %RSD)	<= 1.0	<= 1.0
Injector Carryover (Area %)	<= 0.1	<= 0.1
Conductivity Linearity (Corr.)	>= 0.999	>= 0.999
Conductivity Linearity (%RSD)	<= 5.0	<= 5.0
Injector Linearity (Corr.)	>= 0.999	>= 0.999
Injector Linearity (%RSD)	<= 1.0	<= 1.0
Eluent Generator Step Current (mA)	See Worksheet(s)	See Worksheet(s)
Pump Noise (%)		
Pump Flow Accuracy (mL/min)	<= 0.05	<= 0.05
Pump Flow Precision (%RSD)	<= 2.0%	<= 2.0%
Heater Temperature Verification	<= 2.5	<= 2.5

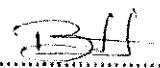
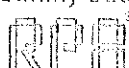
• Additional Information

Customer/Company:	SGS del Peru	Date:	18-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

Dionex

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Specification
Printed: 20/1/2021 2:45 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Injector Carryover:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Isocratic)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14061177	1.1.0
Autosampler	AS-AP (PushSeqPartia	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 6	Nitrate, 1000 ppm		201006
Blank	Water		
Eluent A	Water		

• Additional Information

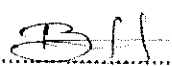
Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period Between Qualification:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Injector Carryover (Area %)	PASS

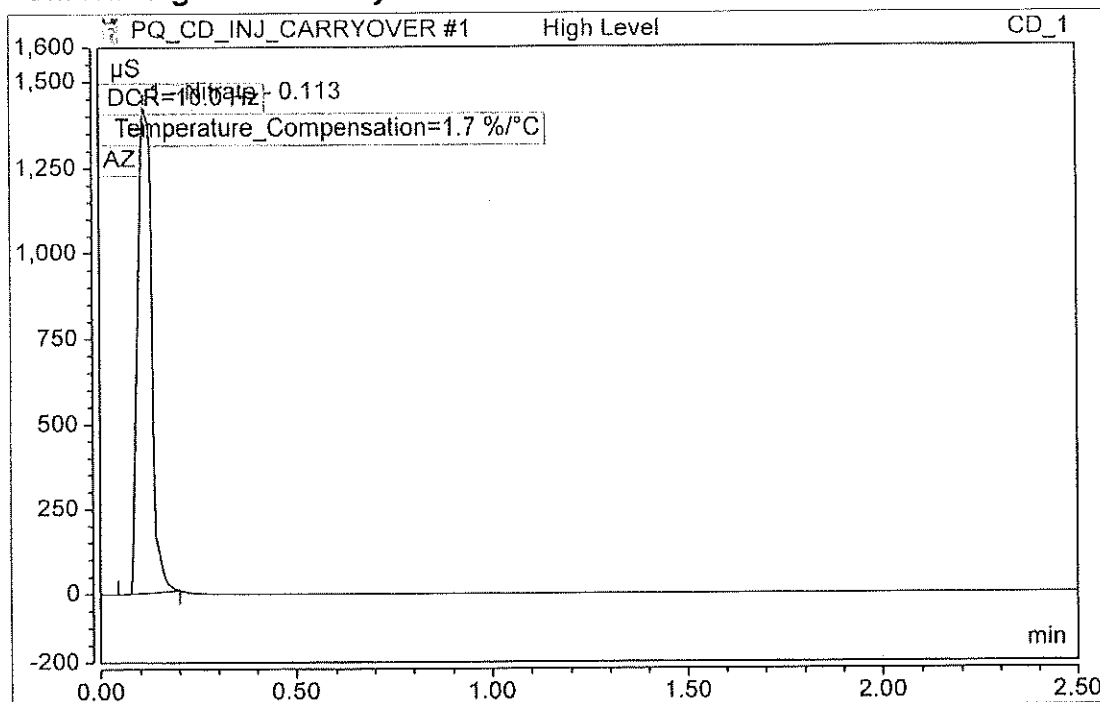
Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
RPA® Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Carry_Over
Printed: 20/1/2021 2:53 p. m.

• **Chromatogram for Carryover Test**



• **Data for Carryover Test**

Name	Ret. Time (detected) min	Area μS*min
	CD_1	CD_1
	Nitrate	Nitrate
High Level	0.11	58.232
Water	0.11	0.082
Water	0.11	0.062
Carryover: (%)		0.0
Limit: (%)		0.1
Result:		PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
RPA Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Carry_Over
Printed: 20/1/2021 2:53 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Detector Linearity:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Isocratic)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1. 1. 0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14061177	1. 1. 0
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 1	Nitrate, 5 ppm		201006
ECD Sample 2	Nitrate, 10 ppm		201006
ECD Sample 3	Nitrate, 25 ppm		201006
ECD Sample 4	Nitrate, 50 ppm		201006
ECD Sample 5	Nitrate, 100 ppm		201006
Eluent A	Water		

• Additional Information

Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Conductivity Linearity (Corr.)	PASS
Conductivity Linearity (%RSD)	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Bustamante P
RPA Soporte Técnico

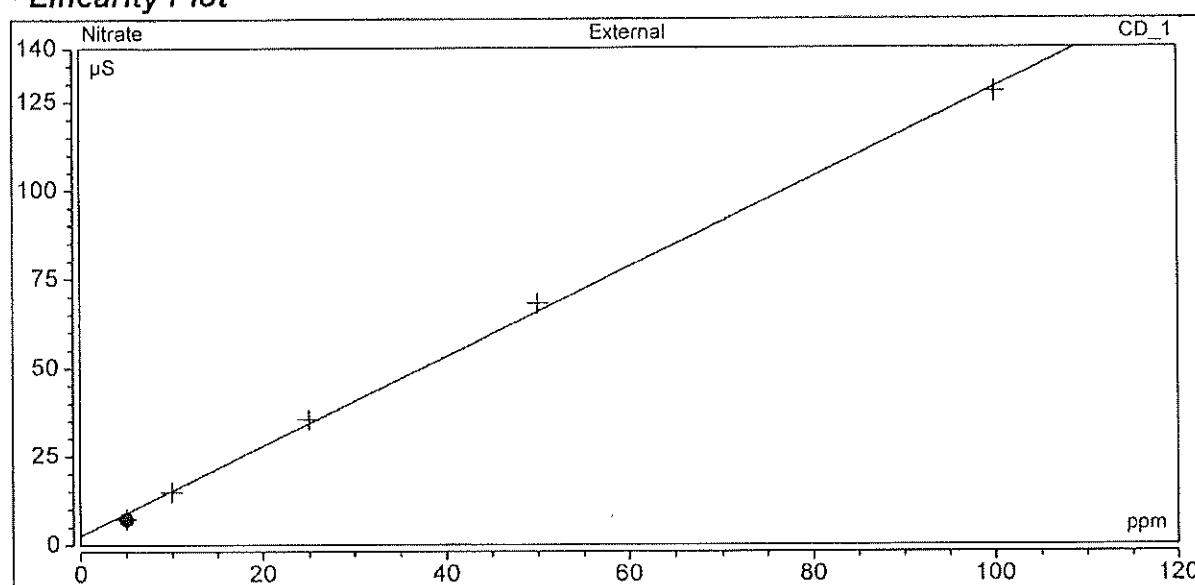
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Det_Linearity
Printed: 20/1/2021 2:55 p. m.

• **Data for Detector Linearity**

Sample Name	Amount n.a.	Height μ S CD_1 Nitrate	Residual CD_1 Nitrate
Detector linearity_1	5.0000	7.3247	-1.6724
Detector linearity_2	10.0000	14.8766	-0.4310
Detector linearity_3	25.0000	35.3768	1.1376
Detector linearity_4	50.0000	68.0390	2.2470
Detector linearity_5	100.0000	127.6162	-1.2812
Variance			3.656
Standard Deviation			1.912

• **Linearity Plot**



Cal. Type	Number of Points	Offset	Slope
Lin, WithOffset	5	2.687	1.262

	Correlation Coefficient	% RSD
Linearity	0.999	3.8
Limit:	0.999	5.0
Result:	PASS	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Det_Linearity
Printed: 20/1/2021 2:55 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

EG Current Test:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Eluent Generator	ICS-5000(+) EG (EGC K2CO3	Thermo Fisher	11071069	1. 0. 0

• Accessories

Name	Description	Vendor	Lot / Serial
IC Qualification Test Box	Test Box II		18020705
Ammeter / Multimeter	Fluke 179		19320093

• Additional Information

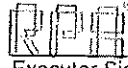
Customer/Company:	SGS del Peru	Date:	18-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Cartridge Position	Cartridge Type	Result
EGC Current	EGC_1	EGC K2CO3	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


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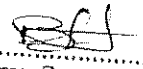
OQ_PQ_Modular_Validation / EG_Current
Printed: 20/1/2021 3:03 p. m.

• Data for ICS-5000(+) EG (EGC K₂CO₃) Current Qualification Test

Concentration (mM)	Theoretical Current (mA)	Measured Current (mA)	Limit (+/-)	Deviation	Result
	0.00	0.00	1.00	0.00	PASS
	3.22	3.22	1.00	0.00	PASS
	6.43	6.43	1.00	0.00	PASS
	9.65	9.65	1.20	0.00	PASS
	12.86	12.86	1.40	0.00	PASS
	16.08	16.08	2.00	0.00	PASS
	19.30	19.30	2.00	0.00	PASS
	22.51	22.51	2.60	0.00	PASS
	25.73	25.73	3.20	0.00	PASS
	28.95	28.95	3.80	0.01	PASS
	32.16	32.16	4.60	0.00	PASS
	35.38	35.38	5.20	0.00	PASS
	38.59	38.59	6.40	0.00	PASS
	41.81	41.81	7.60	0.00	PASS
	45.03	45.03	10.40	0.00	PASS
	48.24	48.24	12.80	0.00	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
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Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / EG_Current
Printed: 20/1/2021 3:03 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Pump Flow Rate Accuracy and Precision Test:

• Instruments and Fluidics

Analytical Mode

Instrument Name	Model	Supplier	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Isocratic)	Thermo Fisher	11071122	6.1.0
Chromeleon	7.2.10.23925	Thermo Fisher	2197	n.a.

• Accessories:

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
Balance			

• Limits:

Test	Customized Limits	Thermo Fisher Rec. Limits
Pump Flow Accuracy (mL/min)	0.05	0.05
Pump Flow Precision (%RSD)	<= 2.0	<= 2.0

• Additional Information:

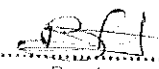
Customer/Company:	SGS del Peru	Date:	18-Ene.-2021
Qualification	Jimmy Bustamante	Period between Qualifications:	12 months
Executor/Company:	/RPA	Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Pump Flow Accuracy (mL/min)	PASS
Pump Flow Precision (%RSD)	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico
Executor Signature _____ Date _____

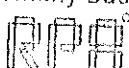
OQ_PQ_Modular_Validation / Flow_Rate
Printed: 20/1/2021 2:51 p. m.

• **Data for Pump Flow Rate Accuracy and Precision Test**

Temperature (°C)		23			
Segment	Measured Eluent Weight (g)	Calculated Eluent Flow Rate (mL/min)	Deviation from 1.00 mL/min	Limit	Result
0	33.879	-	-	-	-
1	38.865	1.000	0.000	0.05	PASS
2	43.857	1.001	0.001	0.05	PASS
3	48.843	1.000	0.000	0.05	PASS
4	53.831	1.000	0.000	0.05	PASS
5	58.825	1.001	0.001	0.05	PASS
Average		1.000		Overall	PASS
Standard Deviation		0.001			
% RSD		0.1			

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Flow_Rate
Printed: 20/1/2021 2:51 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Injector Linearity:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Isocratic)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14061177	1.1.0
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 4	Nitrate, 50 ppm		201006
Eluent A	Water		

• Additional Information

Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Injector Linearity (Corr.)	PASS
Injector Linearity (%RSD)	PASS

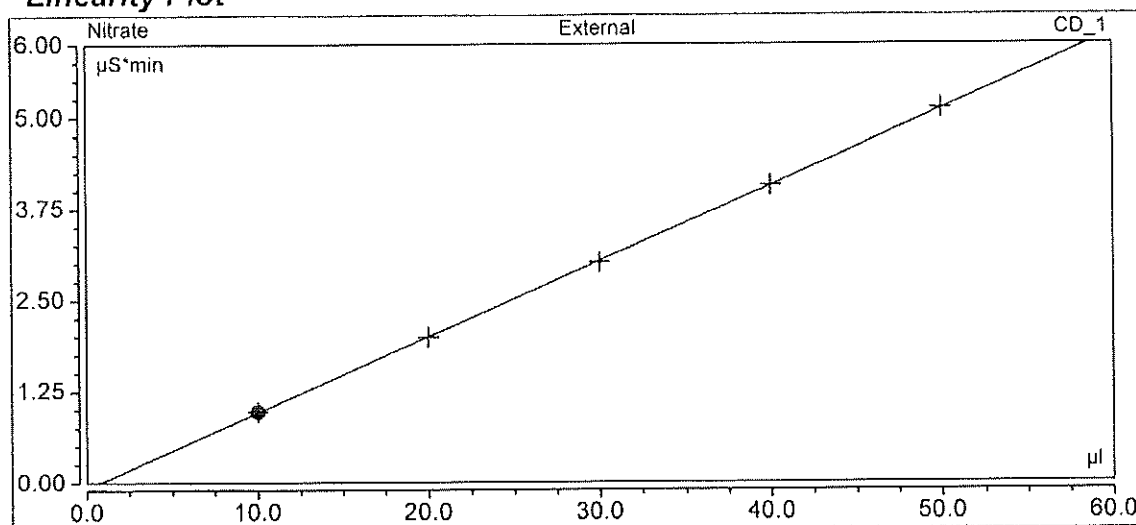
Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Bustamante P
RPA Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Inj_Linearity
Printed: 20/1/2021 2:53 p. m.

• **Linearity Plot**



• **Data for Injector Linearity Test**

Name	Ret. Time (detected) min CD_1 Nitrate	Inj. Vol. μL	Area μS*min CD_1 Nitrate	Residuals CD_1 Nitrate
Injector Linearity_1	0.09	10.0	0.980	0.0136
Injector Linearity_2	0.10	20.0	1.995	-0.0073
Injector Linearity_3	0.11	30.0	3.021	-0.0185
Injector Linearity_4	0.10	40.0	4.080	0.0043
Injector Linearity_5	0.11	50.0	5.120	0.0078
Variance				0.0002
Standard Deviation				0.0148

Cal. Type	Number of Points	Offset	Slope
Lin, WithOffset	5	-0.071	0.104

	Correlation Coefficient	% RSD
Injector Linearity	1.000	0.5
Limit:	0.999	1.0
Result:	PASS	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Bustamante P.
RPA Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Inj_Linearity
Printed: 20/1/2021 2:53 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Injector Precision:

• Instruments and Fluidics

Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Isocratic)	Thermo Fisher	11071122	6.1.0
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14061177	1.1.0
Autosampler	AS-AP (PushSeqPartial)	Thermo Fisher	11071310	1.3.0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
ECD Sample 4	Nitrate, 50 ppm		201006
Eluent A	Water		

• Additional Information

Customer/Company:	SGS del Peru	Date:	15-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period Between Qualification	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Injector Precision (Area %RSD)	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925

Jimmy Bustamante P.
RPA Soporte Técnico
Executor Signature _____ Date _____

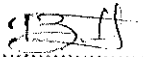
OQ_PQ_Modular_Validation / Inj_Precision
Printed: 20/1/2021 2:54 p. m.

• **Data for Injector Precision Test**

Injector Precision	
Name	Area $\mu\text{S} \cdot \text{min}$ CD_1 Nitrate
Inj Precision_1	2.497
Inj Precision_2	2.490
Inj Precision_3	2.472
Inj Precision_4	2.506
Inj Precision_5	2.489
Inj Precision_6	2.477
Inj Precision_7	2.501
Inj Precision_8	2.493
Inj Precision_9	2.486
Inj Precision_10	2.493
Average:	2.490
Std Dev:	0.010
% RSD:	0.4
Limit:	1.0
Result:	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Inj_Precision
Printed: 20/1/2021 2:54 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Conductivity Detector Noise and Drift:

• Instruments and Fluidics Analytical Mode

Instrument name	Model	Supplier's Name	Serial Number	Moduleware Version
Pump	ICS-5000(+) DP (Isocratic)	Thermo Fisher	11071122	6.1.0
Absorbance Detector	n.a.	Thermo Fisher	n.a.	n.a.
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14061177	1. 1. 0

• Accessories

Name	Description	Vendor	Lot / Serial
Backpressure Tubing	0.075 mm (0.003") ID PEEK, 99 cm (39")		
Eluent	Water		

• Additional Information

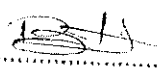
Customer/Company:	SGS del Peru	Date:	18-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period Between Qualification	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Noise	PASS
Drift	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P.
RPA Soporte Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Noise_and_Drift
Printed: 20/1/2021 2:57 p. m.

• **Data for Detector Noise**

Segment No.	Noise, nS
1	1.06
2	0.54
3	1.94
4	0.82
5	0.55
6	0.53
7	0.62
8	0.52
9	0.60
10	0.69
11	0.77
12	0.68
13	1.03
14	1.09
15	0.68
16	0.68
17	0.60
18	0.90
19	0.51
20	0.51
Average, nS	0.8
Limit, nS	2.0
Result	PASS

• **Data for Detector Drift**

20 Minute Drift, nS	Drift, nS/hr	Limit, nS/hr	Result
5.5	16.5	20.0	PASS

Customer Signature _____ Date _____

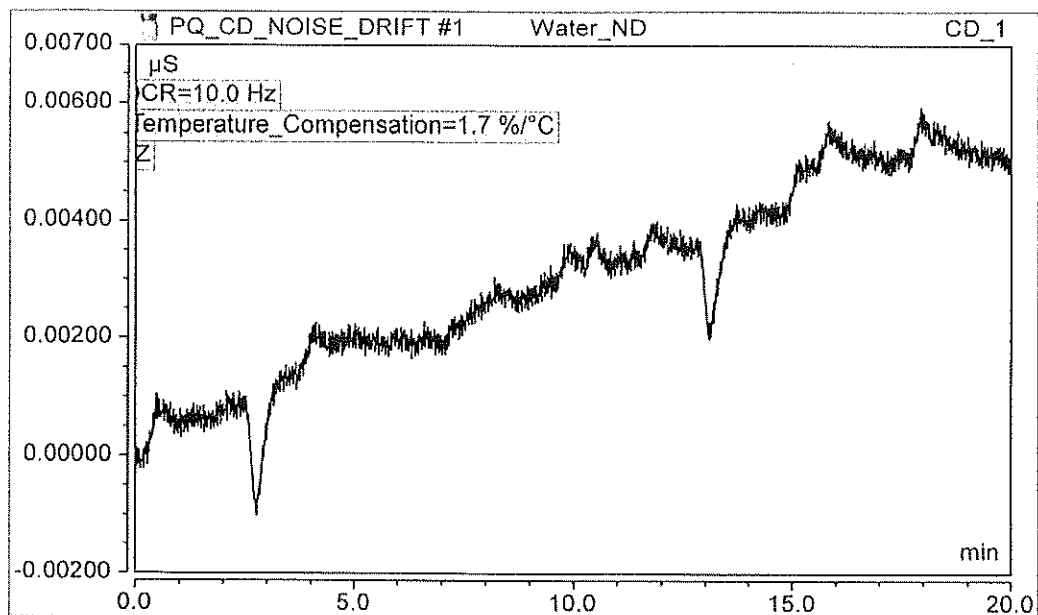
Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P.
RPA SopORTE
Técnico

Executor Signature _____ Date _____

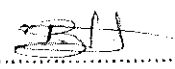
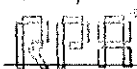
OQ_PQ_Modular_Validation / Noise_and_Drift
Printed: 20/1/2021 2:57 p. m.

• *Chromatogram of Detector Noise and Drift*



Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P
 Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Noise_and_Drift
Printed: 20/1/2021 2:57 p. m.



Performance Qualification Rev. 7.30 for Chromeleon 7.2

Column Heater Temperature Verification:

• Instruments

Analytical Mode

Instrument Name	Model	Supplier	Serial Number	Moduleware Version
Thermal or Detector Compartment	ICS-5000(+) DC	Thermo Fisher	11071045	1.1.0
Conductivity Detector	ICS-5000(+) CD	Thermo Fisher	14061177	1.1.0

• Accessories

Name	Description	Vendor	Lot / Serial
Temperature Probe	Fluke 179		19320093

• Additional Information

Customer/Company:	SGS del Peru	Date:	18-Ene.-2021
Qualification Executor/Company:	Jimmy Bustamante /RPA	Period Between Qualifications:	12 months
		Next Qualification:	Ene.-2022

• Test Results Summary

Test	Result
Heater Temperature Verification	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P

 Soporte
Técnico
Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Temperature
Printed: 20/1/2021 3:05 p. m.

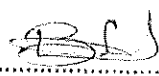
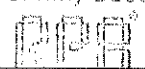
• **Data for Column Heater Temperature**

Measured Column Temperature (°C)	30.30
Measured Compartment Temperature (°C)	20.10

	Theoretical Temp (°C)	Difference (°C)	Limit (+/-)	Result
Column Heater Temperature (°C)	30.00	-0.30	<= 2.5	PASS
Compartment Heater Temperature (°C)	20.00	-0.10	<= 2.5	PASS

Customer Signature _____ Date _____

Chromeleon(c)Thermo Fisher
v.7.2.10.23925


Jimmy Bustamante P.
 Soporte
Técnico

Executor Signature _____ Date _____

OQ_PQ_Modular_Validation / Temperature
Printed: 20/1/2021 3:05 p. m.

Thermo SCIENTIFIC CERTIFICATE OF CONFORMITY

IC QUALIFICATION TEST BOX II (22000-60001)

This certificate validates that the product values referenced below meet or exceed all Thermo Scientific functional specifications and release requirements.

Instrument Serial Number: 18020705

TEST BOX LOADS AND FUNCTIONS

☒ AES	100Ω +/- 5%	☒ CR-TC 3-pin ANA INT	250Ω +/- 5%
☒ EGC CAP KOH	100Ω +/- 5%	☒ CR-TC 3-pin CAP INT	10kΩ +/- 1%
☒ EGC CAP MSA	100Ω +/- 5%	☒ CR-TC 4-pin ANA INT	250Ω +/- 5%
☒ EGC ANA KOH	100Ω +/- 5%	☒ CR-TC 4-pin CAP INT	10kΩ +/- 1%
☒ EGC ANA MSA	100Ω +/- 5%	☒ EGC - Memory Test	
☒ ERS (CC)	12Ω +/- 5%	☒ ERS - Memory Test	
☒ ERS (CV)	250Ω +/- 5%	☒ CR-TC - Memory Test	

Tester: *[Signature]*

Date: 21FEB2020

Calibration valid 2 years after this date

P/N 22000-97001 A

Pag.01

CERTIFICADO DE CALIBRACIÓN No. 20-387

Cliente: REACTIVOS PARA ANALISIS S.A.C.
Equipo: MULTIMETRO DIGITAL MARCA FLUKE
Modelo: 179 N/S 19320093

Nosotros, FERRIER S.A. con domicilio en Jr. Pietro Torrigiano 166- SAN BORJA, declaramos que este producto ha sido calibrado en conformidad con los estándares de calidad sugeridos por FLUKE INTERNATIONAL CORPORATION, y con la respectiva trazabilidad a NIST (The National Institute of Standards and Technology-USA).

FECHA DE CALIBRACION: 30 de Junio del 2020
LUGAR DE CALIBRACION: Laboratorio de FERRIER S.A.

METODO Y PATRON DE MEDICION UTILIZADOS:
Determinación del error por comparación con nuestro Multicalibrador Marca FLUKE modelo 5522A N/S 2714904 con trazabilidad a patrones NIST.

Certificado de Calibración: CERTIFICATE NUMBER EVL611755

CONDICIONES DE CALIBRACION:

Humedad relativa: 61%
Temperatura : 25°C

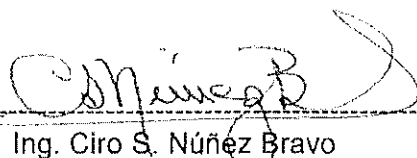
CONCLUSION:

Los errores encontrados en todas las funciones del instrumento no superaron las tolerancias establecidas por el fabricante.
Se adjuntan datos de las mediciones.
La incertidumbre de la medición ha sido determinada con un factor de cobertura $K = 2$ para un nivel de confianza de 95%.

OBSERVACIONES Y RECOMENDACIONES:

FLUKE CORPORATION recomienda la calibración anual del equipo.
FERRIER S.A.

Ing. Aldo Bravo Lee
Responsable de Calibración


Ing. Ciro S. Núñez Bravo
Gerente**FERRIER S.A.****Teléfonos****E-mail****Web**

Jr. Pietro Torrigiano 166 - SAN BORJA
R.U.C. 20414675761

4750505 / 2268056 / 2232015 / 4753639
2232132 / Ventas: 985607879

ferrier@ferriersa.com.pe

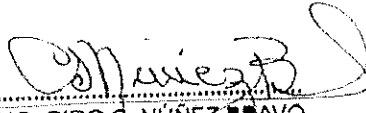
www.ferriersa.com.pe

CERTIFICADO DE CALIBRACION

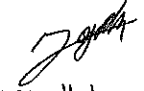
No. 20-387

CLIENTE: REACTIVOS PARA ANALISIS S.A.C.
EQUIPO: MULTIMETRO DIGITAL MARCA FLUKE
MODELO: 179 N/S 19320093
FECHA: 30/06/2020

FUNCION	ENTRADA	FRECUENCIA	LIMITE INFERIOR	LECTURA	LIMITE SUPERIOR	INCERTIDUMBRE (%)	ERROR (%)
ACV	300 mv	45 Hz	296.7	300.0	303.3	0.39	0.00
ACV	5 V	500 Hz	4.947	4.954	5.053	0.45	-0.92
ACV	5 V	1 kHz	4.897	4.954	5.103	0.28	-0.92
ACV	50 V	45 Hz	49.47	49.95	50.53	0.08	-0.10
ACV	50 V	1 kHz	48.97	50.07	51.03	0.08	0.14
ACV	100 V	1 kHz	97.7	100.3	102.3	0.19	0.30
ACV	300 V	45 Hz	296.7	299.8	303.3	0.14	-0.07
ACV	600 V	1 kHz	587.7	600.6	612.3	0.11	0.10
ACV	1000 V	45 Hz	987	996	1013	0.32	-0.40
Frecuency	20 kHz	1.5 V	19.97	20.00	20.03	0.04	0.00
Frecuency	50 kHz	5V	49.95	50.00	50.05	0.02	0.00
DCV	5 V		4.993	5.000	5.007	0.03	0.00
DCV	300 V		299.6	300.0	300.4	0.03	0.00
DCV	1000 V		997	1000	1003	0.08	0.00
DCV	-1000 V		-1003	-1000	-997	0.08	0.00
DC mv	30 mV		29.8	30.0	30.2	0.27	0.00
DC mv	-300 mV		-300.4	-299.9	-299.6	0.04	-0.03
DC mv	600 mV		599.3	599.8	600.7	0.03	-0.03
Ohms	19 ohmios		18.6	19.1	19.4	0.72	0.53
Ohms	19 Megohms		18.69	19.02	19.31	0.28	0.11
Capacitance	900 nF		887	900	913	0.29	0.00
AC A	4 A	45 Hz	3.937	4.002	4.063	0.09	0.05
AC A	9 A	1 kHz	8.84	9.00	9.16	0.37	0.00
AC mA	3 mA	45 Hz	2.93	3.02	3.07	0.45	0.67
AC mA	50 mA	1 kHz	49.22	49.99	50.78	0.10	-0.02
AC mA	400 mA	1 kHz	393.7	399.8	406.3	0.11	-0.05
DCA	4 A		3.957	4.000	4.043	0.08	0.00
DCA	-9 A		-9.12	-9.00	-8.88	0.11	0.00
DC mA	3 mA		2.94	3.02	3.06	0.35	0.67
DC mA	50 mA		49.47	50.00	50.53	0.04	0.00
DC mA	-400 mA		-404.3	-400.0	-395.7	0.04	0.00
Temp	-40 °C		-41.4	-39.9	-38.6	0.91	-0.25
Temp	100 °C		98.9	100.1	101.1	0.27	0.10
Temp	191 °C		188.1	191.1	193.9	0.21	0.05
Temp	200 °C		197.0	200.0	203.0	0.20	0.00


ING. CIRO S. NÚÑEZ BRAVO
CIP 46601
FERRIER S.A.
Gerente General

A. B. L.


Julio Hector
Ojeda Velarde

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