

**CERTIFICATE OF ANALYSIS**  
**Benzodiazepines**

Product Name	Abbott Alinity c Benzodiazepines Reagent Kit
Abbott Material Number	09P6220
Microgenics Part Number	10024835
Abbott Lot Number	38944FD01
Storage Conditions	2 - 8 °C
Date of Manufacture (YYYY-MM-DD)	2022-05-27
Kit Expiration Date (YYYY-MM-DD)	2023-08-31
Total Quantity	967
Package Insert Commodity Number and Revision	H05941R01

**Non-functional Testing**

Evaluation	Specifications	Results	Pass/Fail
Appearance	Reagent 1: Clear solution free of any foreign material and substantially free of intrinsic particulate matter	Reagent 1: Clear solution free of any foreign material and substantially free of intrinsic particulate matter	Pass
Appearance	Reagent 2: Clear solution free of any foreign material and substantially free of intrinsic particulate matter	Reagent 2: Clear solution free of any foreign material and substantially free of intrinsic particulate matter	Pass
Minimum Fill Volume	Reagent 1: Minimum Fill $\geq$ 32.6 mL	> 32.6 mL	Pass
Minimum Fill Volume	Reagent 2: Minimum Fill $\geq$ 32.2 mL	> 32.2 mL	Pass
Label Claim Volume	Reagent 1: Label Claim = 32.2 mL	32.2 mL	Pass
Label Claim Volume	Reagent 2: Label Claim = 31.8 mL	31.8 mL	Pass

**Barcode Verification:** The following information was verified by Reagent Scan on Alinity c

Assay	Specifications	Results	Pass/Fail
Benzodiazepines	Acceptable Verification on Alinity c Instrument - Complies with the requirements specified on current PSCP	Acceptable Verification on Alinity c Instrument - Complies with the requirements specified on current PSCP	Pass

**Functional Testing:** Testing was performed with final barcode labeled product on the Alinity c

Material Specification Requirement	Specification (mA/min)	Run 1	Run 2	Pass/Fail
DOA Frozen Anchor MC Negative Calibrator Rate	$\geq$ 100	218	218	Pass
DOA Frozen Anchor Benzodiazepine Calibrator 2 - DOA Frozen Anchor MC Negative Calibrator	$\geq$ 50	96	96	Pass
DOA Frozen Anchor Benzodiazepine Calibrator 4 - DOA Frozen Anchor Benzodiazepine Calibrator 2	$\geq$ 50	139	137	Pass

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**CERTIFICATE OF ANALYSIS**  
**Benzodiazepines**

Product Name	Abbott Alinity c Benzodiazepines Reagent Kit
Abbott Material Number	09P5220
Microgenics Part Number	10024835
Abbott Lot Number	38944FD01
Storage Conditions	2 - 8 °C

Control Recovery: Testing was performed with final barcode labeled product on the Alinity c

**Controls**

DOA Frozen Anchor Benzodiazepine Control Level 1	Part Number:	2040	Lot Number:	74453297	Expiration:	2022-11-09
DOA Frozen Anchor Benzodiazepine Control Level 2	Part Number:	10009230	Lot Number:	74453299	Expiration:	2022-11-03

DOA Frozen Anchor Benzodiazepine Controls	Run 1 (ng/mL)	Run 2 (ng/mL)	Grand Mean of all Runs (ng/mL)	Specification (ng/mL)	Pass/Fail
Level 1	161.14	162.01	161.58	≤ 164.96	Pass
Level 2	280.07	279.37	279.72	≥ 231.00	Pass

**Comments:**

NOTE: United States or other non-TSE country in accordance to USDA (per 9 CFR 94.18 (a)): This material was produced in compliance to USDA and/or CPMP/BWP/1230/98 (or amendment as applicable, Guidance in Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal products). It does not contain, nor is derived from Specific Risk Materials as defined in Commission decision 97/534/EC (or successive amendments). This product meets all requirements as stated on the current edition of MS.MASTER342. Quality Signature certifies that the supplied material was manufactured in accordance with Quality System Regulations and passes all Microgenics QC Test Specifications, Microgenics Final Inspection Specifications, and Abbott Acceptance Requirements.

  
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Completed By

  
\_\_\_\_\_  
Quality Approval

06/20/2022  
\_\_\_\_\_  
Date

06/23/2022  
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Date