



Shed A New Light on
Antipsychotic Treatment

MyCare™ Psychiatry Antipsychotic Drug Level Assays

For **fast and efficient**
turnaround time



The official authorized distributor of MyCare™ Psychiatry



MyCare: Rapid, clinically relevant, and results-driven patient care

What is MyCare?

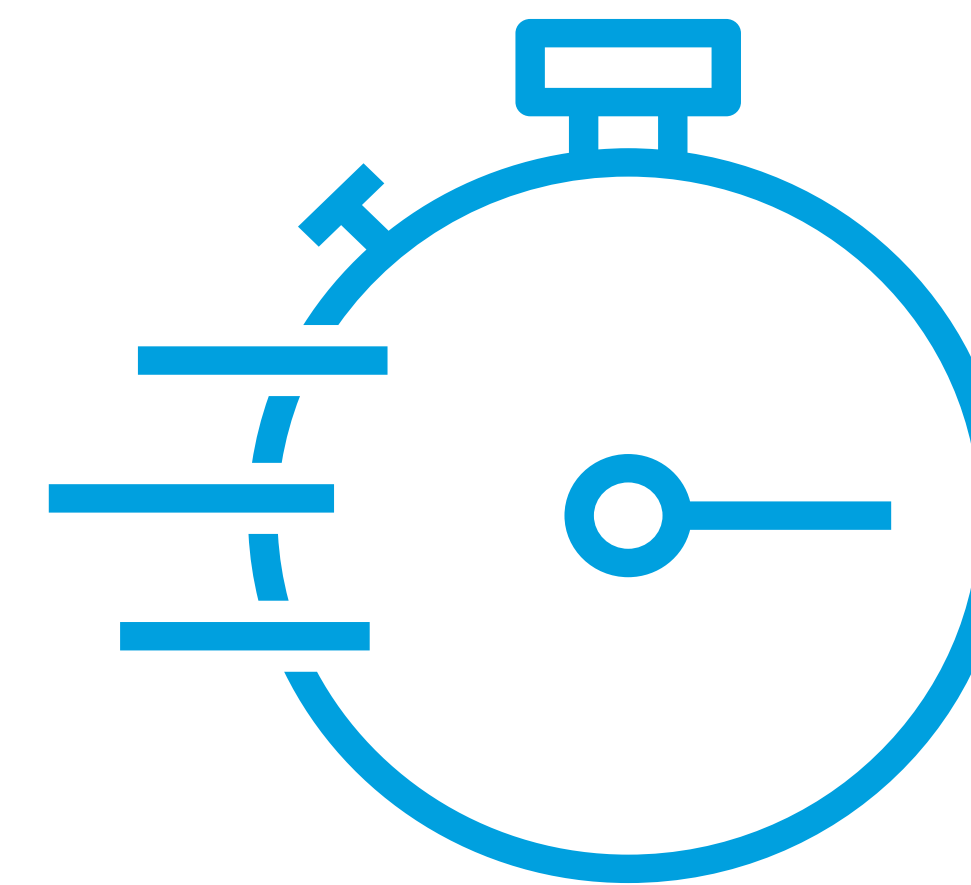
The MyCare™ Psychiatry Drug Assay Kits are intended for the *in vitro* quantitative measurement of **six of the most prescribed antipsychotic drugs** in human serum using automated clinical chemistry analyzers:¹⁻³

- Clozapine
- Aripiprazole
- Risperidone
- Quetiapine
- Paliperidone
- Olanzapine

Why use MyCare?

Therapeutic drug monitoring (TDM) by MyCare offers timely access to **precise, reliable results** to provide clarity on:^{1,3}

- **The causes of treatment failure**
(i.e., medication adherence, drug resistance, drug-drug interactions, and drug metabolism)
- **The causes of worsening symptoms or side effects**
(i.e., medication non-response, non-adherence, new co-medications, aging, changes in habits such as smoking, or nonoptimal dosing)



What are the benefits of MyCare?

MyCare assays are rapid, accurate and easy to perform by laboratory technicians on **automated analyzers already present in clinical labs**. Testing can be performed as routine or STAT and can be offered 24x7 to help improve the care of patients that require these potent medications and assure individualized antipsychotic treatment.³

Please refer to the individual IFUs for further details regarding the assay specifics.



TDM by MyCare Can Help Navigate and Optimize Antipsychotic Treatment

1 Hospitalization and readmission rates in Canada remain high:

Totalling approximately 2 million hospital days annually, schizophrenia and psychotic disorders rank #1 for total length of hospital stay among mental health disorders.⁴ Within 30 days of discharge from hospital, 12% of patients with schizophrenia are readmitted; this figure rises to 38% after 1 year.⁵

- TDM can help evaluate hospital admissions or identify the reason for the admission and help better optimize supportive treatment.

2 Non-adherence with antipsychotic medication remains a significant challenge:

Within 10 days of discharge from hospital, up to 25% of schizophrenia patients are partially or completely non-adherent.⁶ Non-adherence with antipsychotic medication increases to 50% at 1 year and 75% by 2 years post-discharge.⁶

- **TDM can identify patients that are non-adherent permitting health care professionals to facilitate interventions, such as reducing dosages to minimize side effects.**

3 Concurrent illness, concomitant medication, and more lead to interpatient variability:

At the equivalent dose, greater than 20-fold interindividual variation in antipsychotic drug steady-state concentration may result due to concurrent illness, concomitant medication, age, or genetic abnormalities.⁷

- **These potent medications are known to have drug levels impacted by drug-drug interactions, smoking, or concurrent disease. For example, clozapine levels can increase during infections.**

4 The MyCare™ Psychiatry tests are providing the only available automated method to rapidly measure antipsychotic drug levels, providing reliable results that can be compared across health care centers.⁸

* Hiemke et al. defined four levels of recommendations to use TDM ranging from “Level 1: Strongly Recommended” to “Level 4: Potentially Useful”. Among antipsychotics MyCare tests for, TDM is strongly recommended (Level 1) for treatment with clozapine and olanzapine, and recommended (Level 2) for treatment with risperidone, paliperidone, aripiprazole and quetiapine.

TDM by MyCare Can Help Navigate and Optimize Antipsychotic Treatment

Clinical guidelines recommend, or strongly recommend*, routine monitoring of antipsychotic drug levels

- In accordance with the Canadian Schizophrenia Guidelines, mounting evidence reveals that among complementary strategies, TDM is a useful tool to facilitate the ability of clinicians to correctly identify non-adherent patients⁹
- In patients with schizophrenia, research indicates that fluctuations of clozapine concentrations in blood are predictive for relapse⁷
- By increasing doctor's alertness to patient non-compliance, TDM may reduce the risk of relapse⁷
- As TDM considers the interindividual variability of pharmacokinetics, the integration of TDM in routine clinical practice can be leveraged to optimize the safety and efficacy of antipsychotics^{7,10}

* Hiemke et al. defined four levels of recommendations to use TDM ranging from "Level 1: Strongly Recommended" to "Level 4: Potentially Useful". Among antipsychotics MyCare tests for, TDM is strongly recommended (Level 1) for treatment with clozapine and olanzapine, and recommended (Level 2) for treatment with risperidone, paliperidone, aripiprazole and quetiapine.

Clozapine Assay

TEST PARAMETERS

Measuring Range 68 to 1500 ng/mL
 Sample Type plasma / serum

ONBOARD STABILITY*

Calibration Stability 30 days
 Reagent Stability 75 days

*Analyzer Dependent

SHELF LIFE

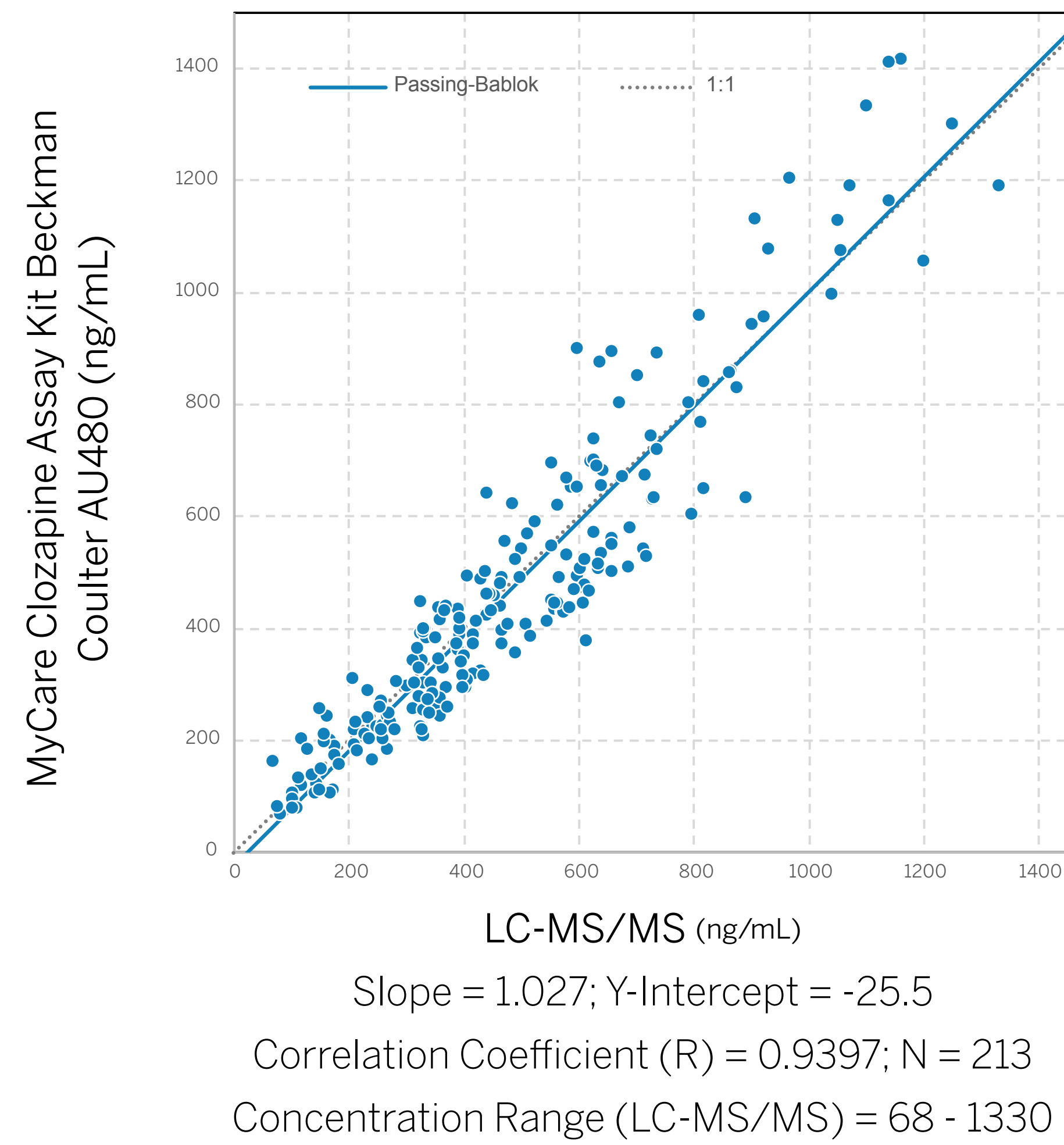
Reagent 10 months
 Calibrators and Controls 10 months

PRECISION

Sample	N	Mean	Repeatability ¹	Within-Laboratory ¹
		(ng/mL)	CV	CV
Control 1	80	156	3.6%	5.7%
Control 2	80	474	2.4%	4.8%
Control 3	80	945	2.9%	5.2%
Clinical 1	80	148	3.6%	6.6%
Clinical 2	80	338	2.2%	4.2%
Clinical 3	80	577	2.6%	4.3%
Clinical 4	80	926	3.6%	5.1%

¹ Verified according to CLSI Guideline EP05-A3

METHOD COMPARISON



Risperidone/Paliperidone Assay

TEST PARAMETERS

Measuring Range 16 to 120 ng/mL
Sample Type serum

ONBOARD STABILITY*

Calibration Stability 30 days
Reagent Stability 60 days

*Analyzer Dependent

SHELF LIFE

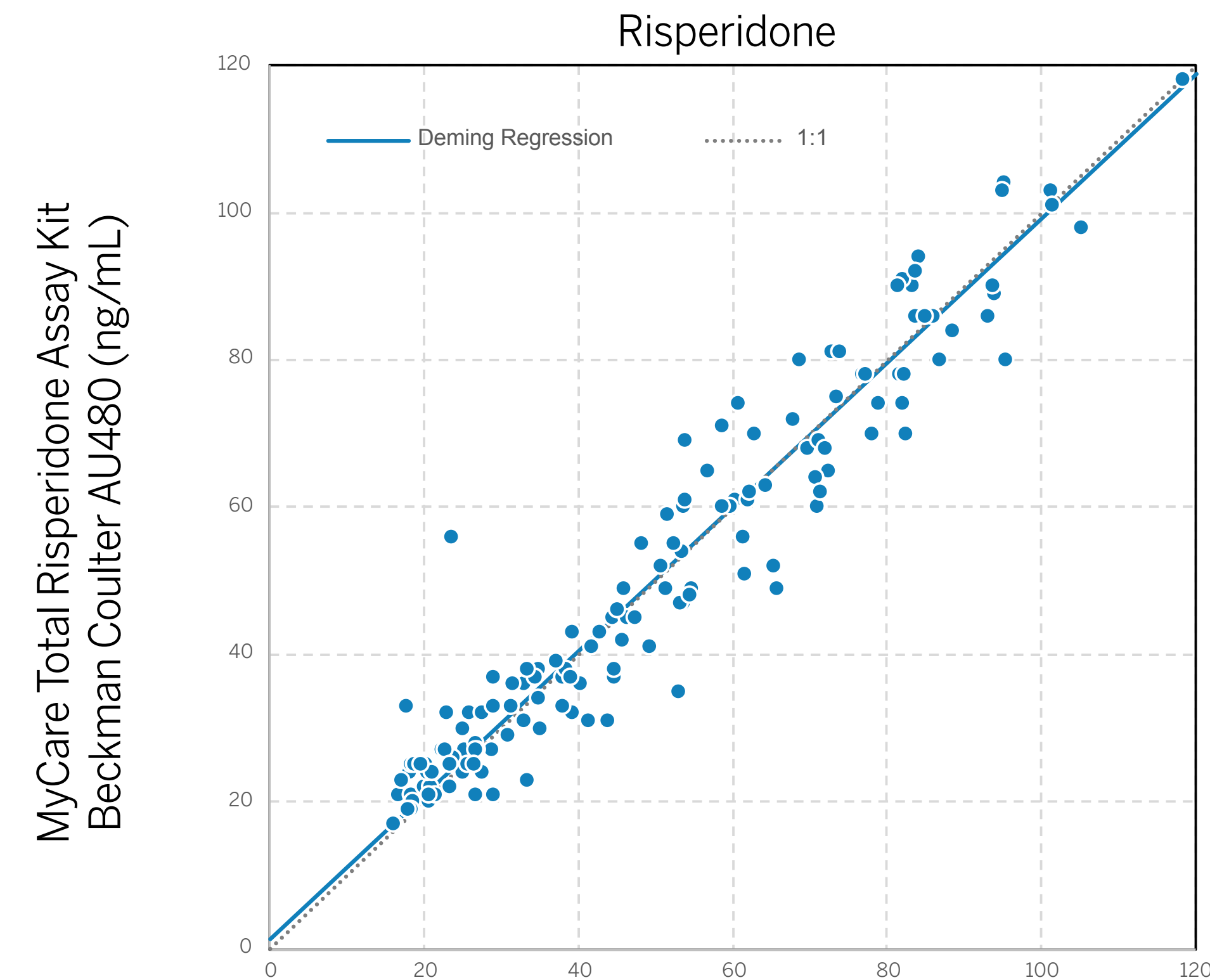
Reagent 10 months
Calibrators and Controls 10 months

PRECISION

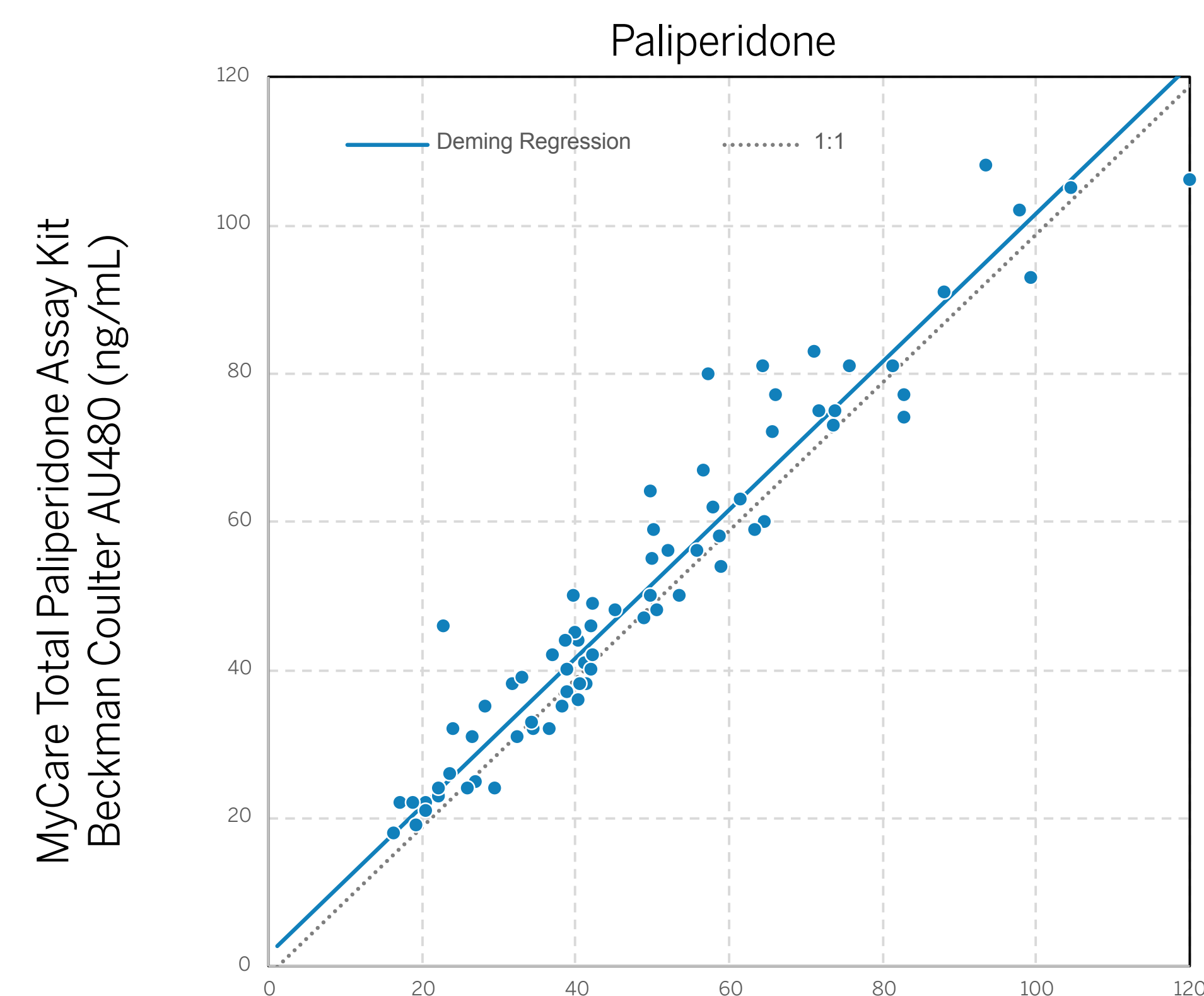
Sample	N	Mean	Repeatability ¹	Within-Laboratory ¹
		(ng/mL)	CV	CV
Control 1	80	36	2.8%	3.7%
Control 2	80	65	2.1%	2.8%
Control 3	80	99	2.5%	3.3%
Serum 1	80	21	3.3%	5.0%
Serum 2	80	59	2.4%	4.2%
Serum 3	80	78	3.3%	6.0%
Clinical 1	80	22	3.0%	4.2%
Clinical 2	80	58	3.1%	3.8%

¹ Verified according to CLSI Guideline EP05-A3

METHOD COMPARISON



Deming Regression Statistics MyCare
Total Risperidone Assay Kit vs. LC-MS/MS
Slope = 0.98; Intercept = 1
Correlation Coefficient (R) = 0.96; N = 146
Concentration Range (LC-MS/MS) = 16 – 118 ng/mL



Deming Regression Statistics MyCare
Total Paliperidone Assay Kit vs. LC-MS/MS
Slope = 1.00; Intercept = 3
Correlation Coefficient (R) = 0.94; N = 119
Concentration Range (LC-MS/MS) = 16-120 ng/mL



Total Aripiprazole Assay

TEST PARAMETERS

Measuring Range 45 to 1000 ng/mL
 Sample Type serum

ONBOARD STABILITY*

Calibration Stability 30 days
 Reagent Stability 90 days

*Analyzer Dependent

SHELF LIFE

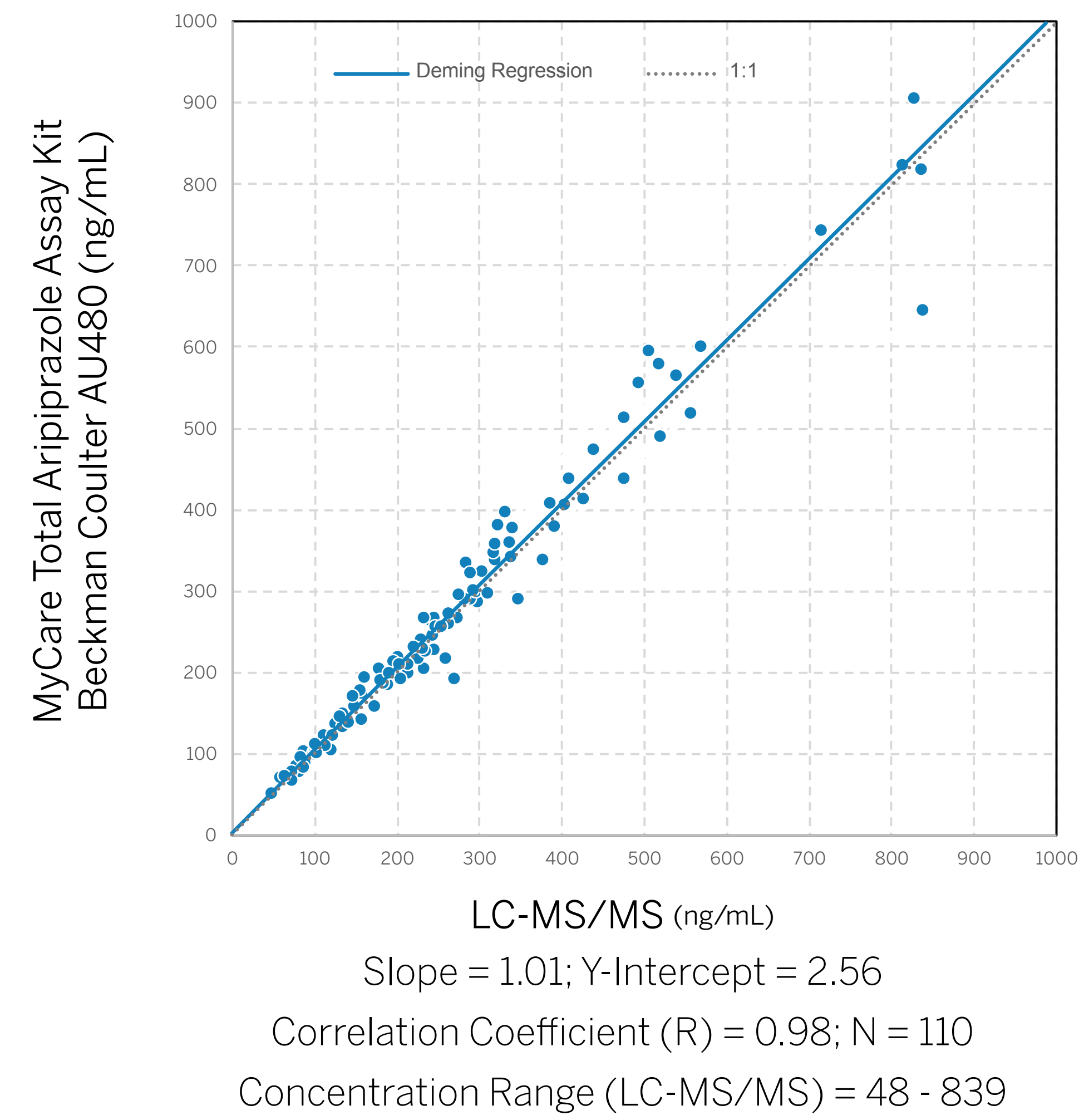
Reagent 10 months
 Calibrators and Controls 10 months

PRECISION

Sample	N	Mean	Repeatability ¹	Within-Laboratory ¹
		(ng/mL)	CV	CV
Control 1	80	49	6.5%	8.3%
Control 2	80	198	2.3%	4.0%
Control 3	80	682	2.2%	3.9%
Serum 1	80	45	6.5%	9.5%
Serum 2	80	959	2.6%	4.3%
Clinical 1	80	150	3.5%	4.1%
Clinical 2	80	503	2.6%	4.1%

¹ Verified according to CLSI Guideline EP05-A3

METHOD COMPARISON



Quetiapine Assay

TEST PARAMETERS

Measuring Range 34 to 700 ng/mL
(2100 with dilution)
Sample Type serum

ONBOARD STABILITY*

Calibration Stability 21 days
Reagent Stability 90 days
*Analyzer Dependent

SHELF LIFE

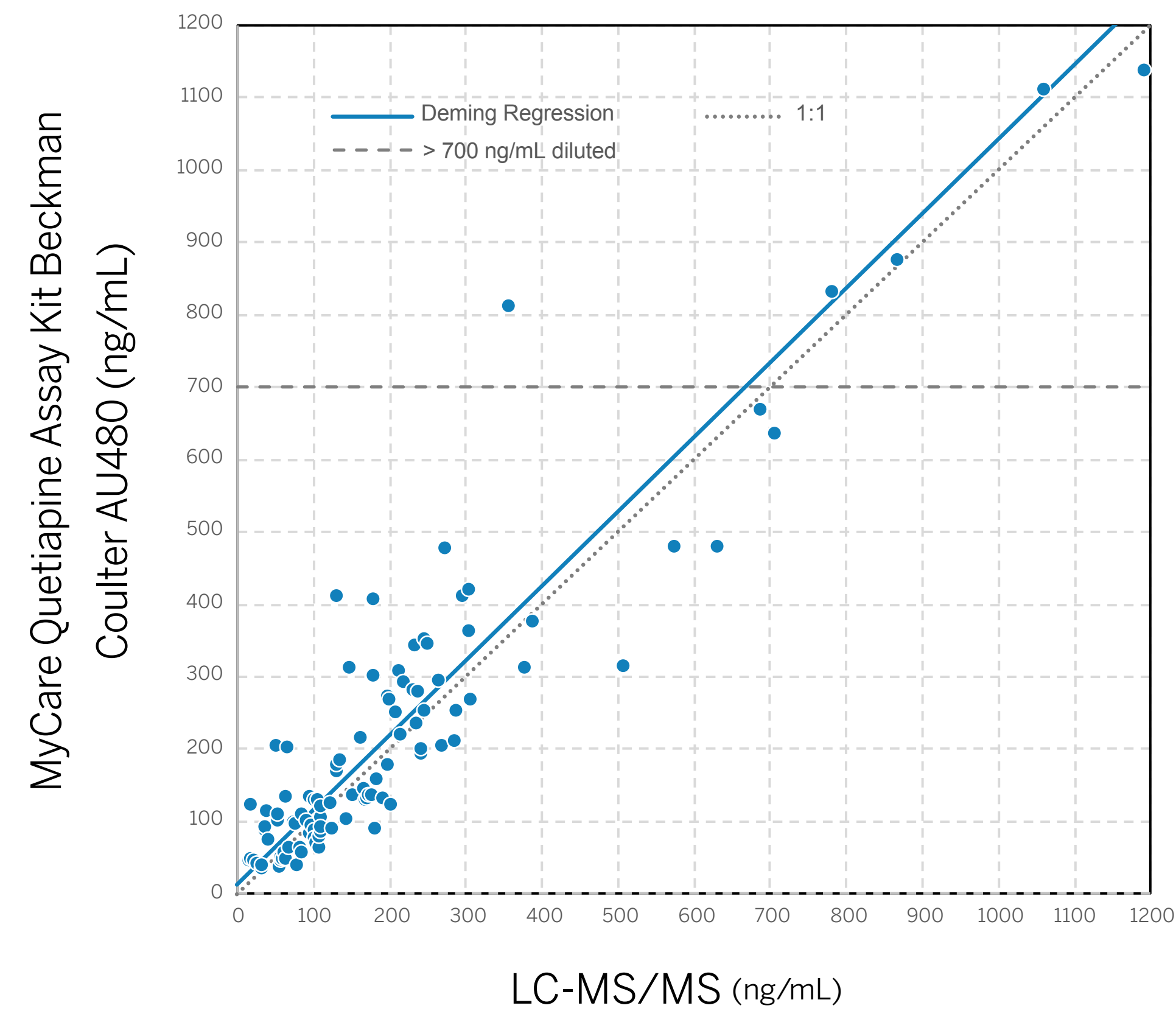
Reagent 10 months
Calibrators and Controls 10 months

PRECISION

Sample	N	Mean	Repeatability ¹	Within-Laboratory ¹
		(ng/mL)	CV	CV
Control 1	80	59	3.4%	7.4%
Control 2	80	317	1.3%	3.7%
Control 3	80	574	1.5%	3.7%
Serum 1	80	51	3.0%	7.9%
Serum 2	80	1002	1.6%	4.6%
Clinical 1	80	91	2.3%	5.6%
Clinical 2	80	506	1.7%	3.5%

¹ Verified according to CLSI Guideline EP05-A3

METHOD COMPARISON



Slope = 1.03; Y-Intercept = 13.55
Correlation Coefficient (R) = 0.92; N = 103
Concentration Range (LC-MS/MS) = 16 – 1192 ng/mL



Olanzapine Assay

TEST PARAMETERS

Measuring Range 22 to 114 ng/mL
(342 with dilution)
Sample Type serum

ONBOARD STABILITY*

Calibration Stability 45 days
Reagent Stability 75 days
*Analyzer Dependent

SHELF LIFE

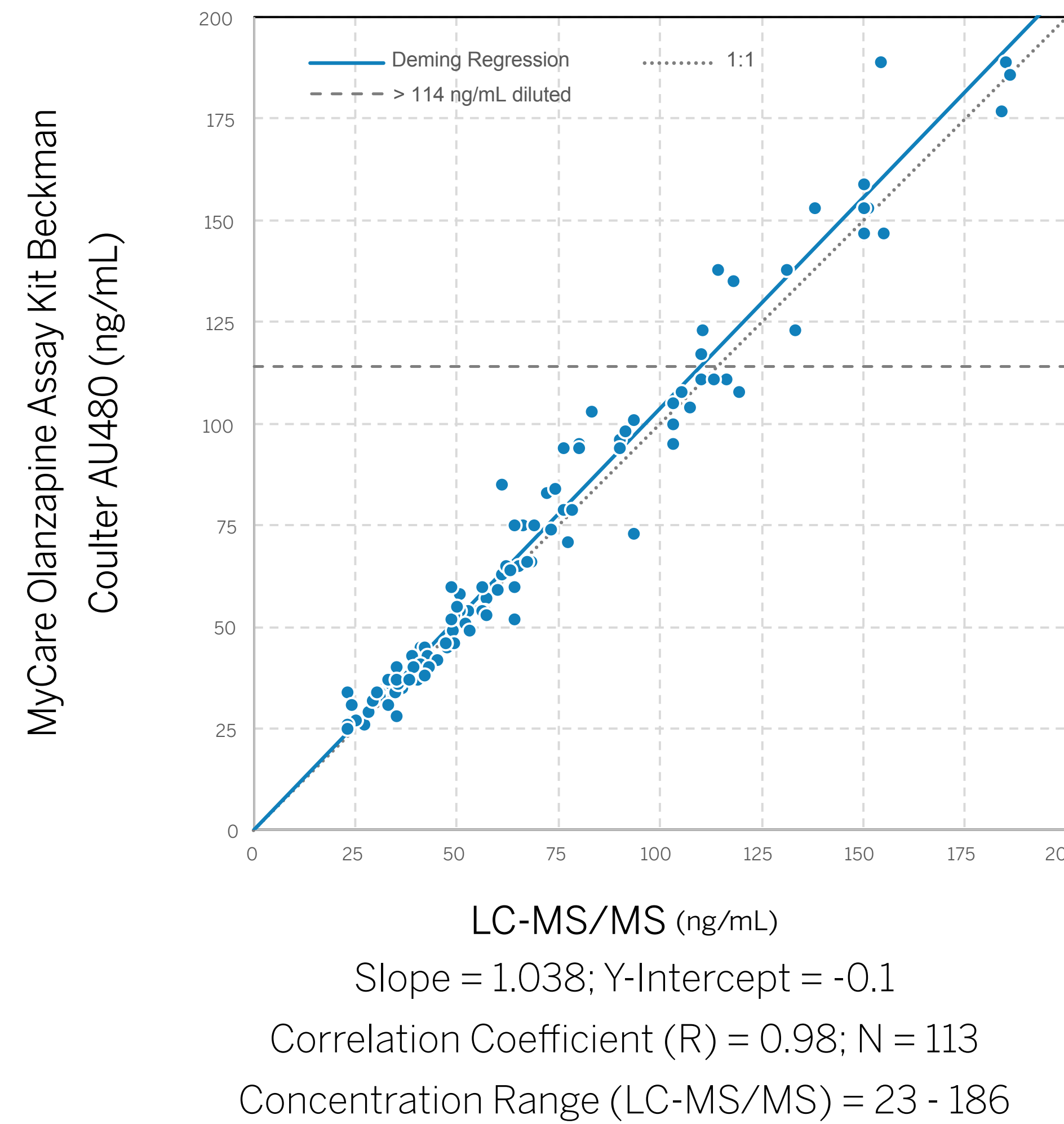
Reagent 10 months
Calibrators and Controls 10 months

PRECISION

Sample	N	Mean	Repeatability ¹	Within-Laboratory ¹
		(ng/mL)	CV	CV
Control 1	80	49	3.1%	4.6%
Control 2	80	106	1.7%	1.9%
Serum 1	80	48	2.9%	3.7%
Serum 2	80	101	1.5%	2.4%
Clinical 1	80	20	5.6%	9.0%
Clinical 2	80	76	2.4%	3.7%

¹ Verified according to CLSI Guideline EP05-A3

METHOD COMPARISON



Ordering Information

ORDER CODES

MyCare™ Psychiatry Clozapine Assay Kit	81026410
MyCare™ Psychiatry Risperidone/Paliperidone Assay Kit	81026399
MyCare™ Psychiatry Total Aripiprazole Assay Kit	81026388
MyCare™ Psychiatry Quetiapine Assay Kit	81026394
MyCare™ Psychiatry Olanzapine Assay Kit	81026412
MyCare™ Psychiatry Calibrator Kit 2*	81026402
MyCare™ Psychiatry Control Kit 2*	81026390

*Universal, for use with all assay kits

To place an order, call or email HLS Therapeutics Inc.

Toll-Free Number: +1(866) 669-2313

Email: HLS-CSR@innomar-strategies.com

Contact Us

General Contact HLS Therapeutics Inc.



+1(844) 457-8729



mycaretests.ca

The MyCare™ Psychiatry Drug Assay Kit is intended for the *in vitro* quantitative measurement of antipsychotic drugs in human serum and plasma using automated clinical chemistry analyzers. Measurements obtained are used for monitoring patient adherence to antipsychotic drug therapy to help ensure appropriate treatment.

References:

1. Saladax MyCare™ Psychiatry Guidebook **2.** IQVIA. Data on File. 2021. **3.** Saladax MyCare™ Psychiatry Tech Sheet **4.** Canadian Institute for Health Information. Chartbook July 2019: Health System Resources for Mental Health and Addictions Care in Canada [Internet]. 2019. Available from: <https://www.cihi.ca/sites/default/files/document/mental-health-chartbook-report-2019-en-web.pdf> **5.** Canadian Institute for Health Information. Analysis in Brief: Hospital Length of Stay and Readmission for Individuals Diagnosed With Schizophrenia: Are They Related? April 17, 2008. **6.** Taylor DM, Barnes TRE, Young AH. The Maudsley prescribing guidelines in psychiatry. 14th ed. Hoboken, NJ: John Wiley & Sons; 2021 **7.** Hiemke C, Bergemann N, Clement HW, Conca A, Deckert J, Domschke K, *et al.* Consensus guidelines for therapeutic drug monitoring in neuropsychopharmacology: Update 2017. *Pharmacopsychiatry*. 2018;51(1-02):9-62. **8.** Lopez LV, Shaikh A, Merson J, Greenberg J, Suckow RF, Kane JM. Accuracy of clinician assessments of medication status in the emergency setting: A comparison of clinician assessment of antipsychotic usage and plasma level determination. *J Clin Psychopharmacol*. 2017;37(3):310-4. **9.** Remington G, Addington D, Honer W, Ismail Z, Raedler T, Teehan M. Guidelines for the pharmacotherapy of schizophrenia in adults. *Can J Psychiatry*. 2017;62(9):604-16. **10.** Schoretsanitis G, Kane JM, Correll CU, Marder SR, Citrome L, Newcomer JW, *et al.* Bloods Levels to Optimize Antipsychotic Treatment in Clinical Practice: A Joint Consensus Statement of the American Society of Clinical Psychopharmacology and the Therapeutic Drug Monitoring Task Force of the Arbeitsgemeinschaft für Neuropsychopharmakologie und Pharmakopsychiatrie. *J Clin Psychiatry* [Internet]. 2020;81(3). Available from: <http://dx.doi.org/10.4088/jcp.19cs13169>

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