

MyCare<sup>tm</sup>  
Psychiatry

Guidebook

# Welcome

## Welcome to MyCare Psychiatry by Saladax Biomedical, Inc.

MyCare Psychiatry rapidly measures the medication levels of antipsychotic drugs in a patient's blood.

More than 2000 psychiatrists, nurses and hospital administrators, like yourself, provided input and direction on this product. One in five said that rapid, quantitative drug level tests would be a “game changer” in patient treatment.

MyCare quickly provides objective data, and when used in combination with other clinical information, may help you make **better-informed decisions** and **enhance shared decision making** between you and your patient.

# Why MyCare™?

## **MyCare supports better-informed treatment decisions.**

MyCare provides greater clarity on the causes of treatment failure (i.e. adherence, drug resistance, drug-drug interactions and drug metabolism) and may help distinguish medication non-response from lack of adherence. This information may help you establish the right medication at the right dose more quickly than you would based solely on patient self-report.

# In this Document

---

<b>1. Using MyCare with my patients</b> .....	<b>1.0</b>
• When might I use MyCare?.....	1.2
• Should I use MyCare with Patients on LAIs?.....	1.3
<b>2. Understanding MyCare results</b> .....	<b>2.0</b>
• What does MyCare measure? .....	2.2
• What is an Expected Value?.....	2.4
• What is a patient-specific baseline value? .....	2.6
• What factors may affect medication levels? .....	2.8
• Can a patient fool the test? .....	2.9
<b>3. Including blood level testing in your clinical decision making</b> .....	<b>3.0</b>
• How might you respond to blood level results? .....	3.2
• How might a result be interpreted? .....	3.3

---

<b>4. Sharing MyCare results</b> .....	<b>4.0</b>
• How might I discuss the results with my patient? .....	4.2
• How might I respond to commonly asked questions from my patient? .....	4.3
<b>5. MyCare technology</b> .....	<b>5.0</b>
• What is the MyCare technology? .....	5.2
• How do I know the test results are reliable? .....	5.3

# 1. Using **MyCare**<sup>TM</sup> with my patients

In this section

---

- When might I use MyCare?
- Should I use MyCare with patients on LAIs?

## When might I use MyCare?

---

MyCare may be used on a routine or ad hoc basis. MyCare may be used when a patient has:

### **Good symptom control and is adherent<sup>1,2</sup>**

To establish a patient-specific baseline value. This value may be used as a reference point when interpreting future results, and may be particularly helpful when a patient's clinical presentation changes.

### **Worsening of symptoms<sup>3</sup>**

To better understand why symptoms are returning (e.g. medication non-response or underexposure, non-adherence, new co-medications, aging, or changes in habits such as smoking).

### **Worsening of side effects<sup>1</sup>**

To better understand the occurrence of side effects (e.g. medication level is high compared to others taking the same medication).

### **A history of relapse or non-adherence<sup>3,4</sup>**

To identify situations when further investigation or closer clinical monitoring is warranted (e.g. lower levels at subsequent appointments).

### **Symptoms in an emergency situation<sup>5</sup>**

To identify which antipsychotic medications a patient is taking and their blood levels before further medication is administered in an emergency department.

## Should I use MyCare with patients on LAIs?

---

### **Assist in selecting an effective drug and dose<sup>6</sup>**

LAIs may be a good choice to aid in patient adherence, however blood levels may be useful to further personalize medication.<sup>7</sup> Patients may be rapid or slow metabolizers, resulting in undesirable blood concentrations of drug.

### **Help in establishing baseline and symptom control**

To establish a patient-specific baseline value. This value may be used as a reference point when interpreting future results, and may be particularly helpful when a patient's clinical presentation changes.

### **LAI cycle management**

Establishing if the LAI is still at steady state near the end of the cycle. This may be useful in light of the potential for high degrees of interpatient variability in drug blood concentrations,<sup>8,9</sup> and the potential for symptom breakthrough if drug levels fall outside of an appropriate range.<sup>10</sup>

Results should always be used in the context of clinical presentation. All treatment decisions should be based on the clinical judgment of the treating health care provider.

## 2. Understanding MyCare™ results

### In this section

---

- What does MyCare measure?
- What is an Expected Value?
- What is a patient-specific baseline value?
- What factors may affect medication levels?
- Can a patient fool the test?

# What does MyCare measure?

MyCare measures the concentration of an antipsychotic drug in patients' blood. Specifically, these tests measure the concentrations of the following drugs and, in some cases, their major metabolites:

Prescribed Drug*	Analytes Measured
Clozapine (Clozaril®)	Clozapine
Olanzapine (Zyprexa®, Zypadhera®, Zyprexa Relprevv®)	Olanzapine
Paliperidone (Invega®, Invega Sustenna®, Invega Trinza®, Xeplion®)	Paliperidone**
Aripiprazole (Abilify®, Abilify Maintena®, Aristada)	Aripiprazole plus dehydroaripiprazole
Quetiapine (Seroquel®, Seroquel XR®)	Quetiapine
Risperidone (Risperdal®, Risperdal Consta®)	Risperidone and 9-hydroxyrisperidone

\*Includes oral and injectable formulations where available

\*\*Paliperidone is also known as 9-hydroxyrisperidone and is an active metabolite of risperidone

Each time you run a test, MyCare provides a **value**: the level of drug in ng/mL. The following information may be helpful in using the results for clinical management:

Type of Information	Example
Medication name	Risperidone - Oral
Dosing frequency per day	Daily
Time since last dose	20-24 hours ago

If the dose of medication is known (dose in milligrams, dosing frequency per day, and time since last dose), MyCare provides a value which may then be referenced against the patient's baseline and may also identify if the value is within **Expected Values** for that dosing regimen.<sup>1,2</sup>

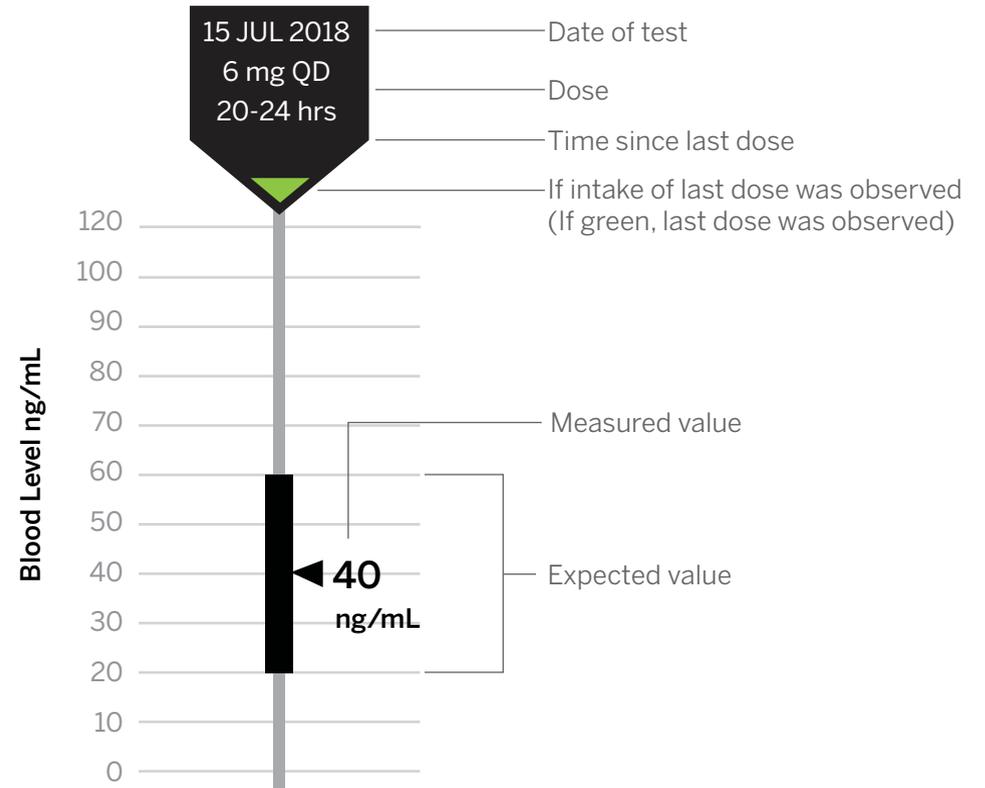
If the medication or dose of medication is unknown (e.g. in an emergency department) MyCare tests are still able to identify and measure the listed antipsychotic drugs.

# What is an Expected Value?

The **Expected Value** is a population-based range defined in the Consensus Guidelines for Therapeutic Drug Monitoring in Neuropsychopharmacology.<sup>1</sup> They are descriptive statistical values specific to each drug formulation. The ranges are based on studies to determine blood levels below which clinical response is less likely and calculations for blood levels expected on the highest recommended dose.<sup>1</sup>

The therapeutic ranges are not fully established. Measured concentrations for adherent patients at steady-state are expected to be in the measuring range of the assay. The complexity of the clinical state, individual differences in sensitivity, and co-administered medications may contribute to different requirements for optimal blood levels. Users should investigate the transferability of the expected values to their own patient population and if necessary determine their own reference range. For diagnostic purposes the test findings should always be assessed in conjunction with the patient's medical history, clinical examinations, and other findings.

To help discuss patient results, the MyCare™ Patient Result Tracking Template is available at [mycaretests.com/downloads/patientresults](https://mycaretests.com/downloads/patientresults). Here is an example use of the template:



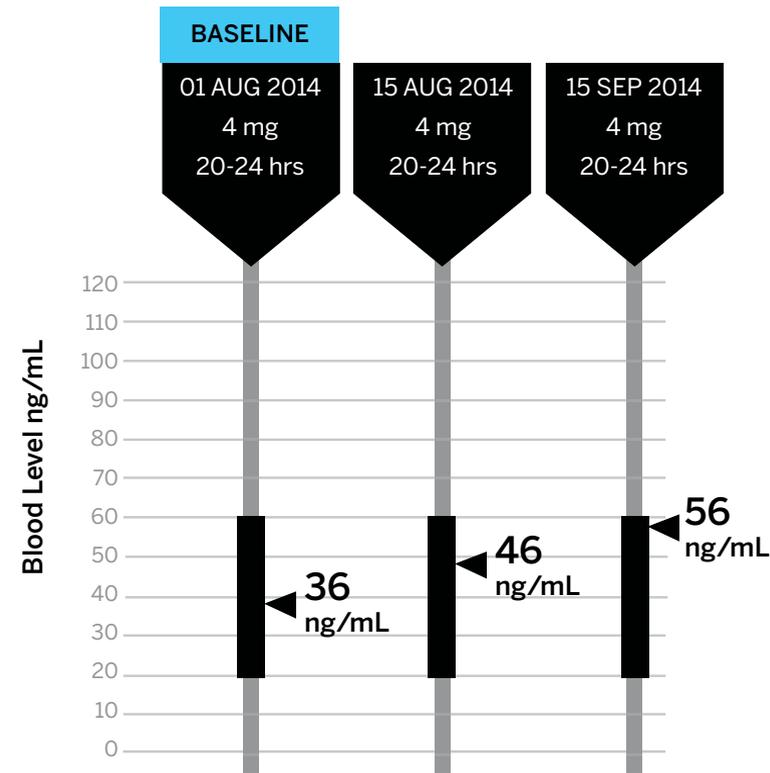
## What is a patient-specific baseline value?

A **patient-specific baseline** is a blood level when a patient has good symptom control and is believed to be adherent to their medication (e.g. in an inpatient setting, direct observation, treatment with LAIs, or during a period of stable treatment).<sup>4</sup> A baseline may help you interpret future results, particularly when a patient's clinical presentation changes.<sup>11</sup>

Unlike population-based values, a baseline value may account for factors unique to each patient that consistently affect their blood levels. For example, a rapid metabolizer may consistently have levels at the low end of the Expected Values.

To use baseline values, they may be saved and displayed on all future reports (blank template forms of the *MyCare™ Patient Result Tracking Template* can be downloaded from website). It is important to re-establish the baseline value if a patient has a change in medication, dose and/or lifestyle habits (e.g. smoking).

To download the *MyCare™ Patient Result Tracking Template*, go to the MyCare website at [mycaretests.com/downloads/patientresults](http://mycaretests.com/downloads/patientresults).



## What factors may affect medication levels?

---

There are a variety of factors to consider when interpreting a result. The most common are:<sup>1</sup>

- Medication adherence (likely, partial, or non-adherence)<sup>4</sup>
- Drug-drug interactions; some drugs like SSRIs may induce metabolism, while others may inhibit metabolism, like carbamazepine<sup>12,13</sup>
- Metabolism (rapid or slow)<sup>14,15</sup>
- Lifestyle changes (smoking, substance use, etc.)<sup>16,17</sup>
- Age<sup>18,19</sup>
- Time since last dose
- Other health issues

Some natural fluctuations in blood levels will occur that are not clinically relevant. For this reason, it is important not to “over-interpret” small changes in serum levels compared to Expected Values or patient-specific baseline values. However, if results are unexpected or do not seem to correspond to clinical observations, it may be appropriate to ask the patient about any changes. If results still seem unexpected, it may be appropriate to repeat the test again in a few days. Small natural variations should average out over several results.

## Can a patient fool the test?

---

No, the patient can not fool the test. The MyCare Psychiatry tests measure exactly how much drug is in the blood (ng/ml). Medication levels are influenced most by the most recent doses.

• Clinical decisions based on blood levels is also known as Therapeutic Drug Monitoring (TDM) As with any TDM, test interpretation is facilitated by knowing:

- Time blood sample is taken
- Time dose is given
- Dosage regimen (dose, duration, dosage form)
- Patient demographics (sex, age, concomitant disease, ethnicity, etc.)
- Comedications
- Indication for monitoring
- Pharmacokinetics and therapeutic range of drug

(Section 3 discusses using blood levels in your decision making)

# 3. Including blood level testing in your clinical decision making

## In this section

---

- How might you respond to blood level results?
- How might a result be interpreted?

## How might you respond to blood level results?

### If the patient is within their Expected Values and has good symptom control:<sup>20</sup>

Positively reinforce treatment adherence.

### If the patient is outside their Expected Values and has good symptom control:<sup>11</sup>

Monitor drug treatment more closely.

### If the patient is below their Expected Values and symptomatic:<sup>1, 3</sup>

- Consider adjusting medication dose
- Explore factors that may be causing poor adherence

### If the patient is within their Expected Values and symptomatic or having side effects:<sup>1, 3, 11</sup>

- Consider adjusting medication dose
- Suggest a different medication formulation, such as an LAI
- Consider changing medications

### If the patient is using an LAI but is symptomatic, blood levels may reflect:<sup>8, 9, 10</sup>

- Long delays to reach steady state
- Rapid or slow metabolism
- Variability resulting from injection site selection, drug administration, or BMI

## How might a result be interpreted?<sup>1, 3, 21</sup>

RESULT	Clinical Presentation		
	Good symptom control	Symptomatic	Having side effects
<b>Above Expected Value</b>	<ul style="list-style-type: none"> <li>• Full adherence</li> </ul>	<ul style="list-style-type: none"> <li>• Non-responder</li> <li>• Higher dose is less likely to improve symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• Dose may be too high</li> </ul>
<b>Within Expected Value</b>	<ul style="list-style-type: none"> <li>• Full adherence</li> </ul>	<ul style="list-style-type: none"> <li>• Non-responder / Partial responder</li> <li>• Lifestyle changes (smoking, drugs, stress, etc.)</li> <li>• Non-efficacious dose</li> <li>• Partial adherence</li> </ul>	<ul style="list-style-type: none"> <li>• Dose may be too high</li> <li>• Medication may not be tolerable at an effective dose</li> </ul>
<b>Below Expected Value</b>	<ul style="list-style-type: none"> <li>• Low level sufficient for clinical response</li> <li>• Partial or non-adherence</li> <li>• Drug-drug interaction</li> <li>• Rapid metabolism</li> <li>• May be at increased risk for worsening of symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• Non-efficacious dose</li> <li>• Partial or non-adherence</li> <li>• Drug-drug interactions (inducers / inhibitors)</li> <li>• Rapid metabolism</li> </ul>	<ul style="list-style-type: none"> <li>• Medication may not be tolerable at an effective dose</li> </ul>

# 4. Sharing MyCare™ results

In this section

---

- How might I discuss the results with my patient?
- How might I respond to commonly asked questions from my patient?

# How might I discuss the results with my patient?

---

## Patient Brochure

Download a Patient Brochure from [mycaretests.com](http://mycaretests.com). Patients want to feel part of the clinical decision process. Their test results offer a great starting point for shared decision making.

The Patient Brochure can be found on the MyCare website at [mycaretests.com/downloads/patientbrochure](http://mycaretests.com/downloads/patientbrochure).

## Printed Result Tracking Template

The *MyCare™ Patient Result Tracking Template* may be used to engage your patient in shared decision making.

For example, you may show the template to your patient during the patient appointment and/or give the template to your patient to take home.

The *MyCare™ Patient Result Tracking Template* can be found on the MyCaretests.com website at [mycaretests.com/downloads/patientresults](http://mycaretests.com/downloads/patientresults). Print the *MyCare™ Patient Result Tracking Template* and use it to fill in your test results.

# How might I respond to commonly asked questions from my patient?

---

Your patients will likely have questions about MyCare. Below are possible responses to commonly asked questions:

## “How often do I have to take the test?”

MyCare is most beneficial when used regularly. Patients' conditions change over time which may affect drug levels. Taking regular levels gives us a starting point if treatment is not going well.

## “What will you do with the results?”

Similar to measuring your cholesterol or blood sugar, we can use MyCare to help you meet your treatment goals and guide decisions about your medication. Just like all of your other medical information, MyCare results are private and protected.

## “Who will explain the results to me?”

Your intake nurse may take your blood sample and run the test, and your treating health care provider will explain the results to you.

## “Will this test report on any other drugs?”

MyCare *only* measures the amount of antipsychotic medication in your body. MyCare isn't able to measure any other drugs, including street drugs.

## “Will it hurt?”

It requires a simple blood draw. It may feel like a quick pinch, but there is usually very little pain afterwards.

# MyCare™ technology

## In this section

---

- What is the MyCare technology?
- How do I know the test results are reliable?

## What is the MyCare technology?

---

The MyCare blood level tests are agglutination inhibition immunoassays; a well-characterized, proven, and trusted technology; one used by leading IVD manufacturers for a variety of drug level testing.

With rapid turn-around time the technology runs on established random access analyzers already used in hospital and reference laboratories.

- No sample pre-treatment
- Random access testing
- Rapid turnaround time

## How do I know the test results are reliable?

---

- Reagents are developed and manufactured in accordance with ISO 13485 and FDA quality system requirements
- Results correlate with established reference methods
- Tests are standardized to certified reference materials

# Contact Us



Email

hello@saladax.com



Phone

+1 (610) 419-6731



Web

mycaretests.com  
saladax.com

Socia Media



@MyCareTests



/SaladaxBiomedical

## Bibliography

- 1 Hiemke C, Bergemann N, Clement HW, et al. Consensus Guidelines for Therapeutic Drug Monitoring in Neuropsychopharmacology: Update 2017. *Pharmacopsychiatry*. 2018;51(1-02):9-62.
- 2 Horvitz-Lennon M, Predmore Z, Mattke S. Personalizing Antipsychotic Treatment of Schizophrenia: Monitoring Plasma Levels for Improved Treatment Decisions. *RAND Corporation*. 2017.
- 3 Horvitz-Lennon M, Mattke S, Predmore Z, Howes OD. The Role of Antipsychotic Plasma Levels in the Treatment of Schizophrenia. *Am J Psychiatry*. 2017;174(5):421-426.
- 4 Meyer JM. Is Monitoring of plasma antipsychotic levels useful? *Current Psychiatry*. 2015;14(11):16.19-20.
- 5 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):310-314.
- 6 Zipursky R, Huynh H, Agid O, Kiang M, Remington G. Can Long-Acting Injectable Pipliperidone Dosing be Optimized with Plasma Level Measurements? *Schizophrenia Bulletin*. 2018;44(suppl\_1):S415-S415.
- 7 Lopez LV, Kane JM. Recommendations for the monitoring of serum concentrations of antipsychotic drugs in the treatment of schizophrenia. *J Clin Psychiatry*. 2015;76(9):1249-1250.
- 8 Helland A, Spigset O. Serum Concentrations of Paliperidone After Administration of the Long-Acting Injectable Form. *Ther Drug Monit*. 2017;39(6):659.
- 9 Castberg I, Spigset O. Serum concentrations of risperidone and 9-hydroxyrisperidone after administration of the long-acting injectable form of risperidone: evidence from a routine therapeutic drug monitoring service. *Ther Drug Monit*. 2005;27(1):103-106.
- 10 Eum S, Schneiderhan ME, Brown JT, Lee AM, Bishop JR. Pharmacogenetic evaluation to assess breakthrough psychosis with aripiprazole long-acting injection: a case report. *BMC Psychiatry*. 2017;17(1):238.
- 11 Bengtsson F. Therapeutic Drug Monitoring of Psychotropic Drugs: TDM "Nouveau". *Ther Drug Monit*. 2004;26(2):145-151.
- 12 Castberg I, Skogvoll E, Spigset O. Quetiapine and drug interactions: evidence from a routine therapeutic drug monitoring service. *J Clin Psychiatry*. 2007;68(10):1540-1545.
- 13 Paulzen M, Eap CB, Grunder G, Kuzin M. Pharmacokinetic Interaction Between Valproic Acid, Meropenem, and Risperidone. *J Clin Psychopharmacol*. 2016;36(1):90-92.
- 14 Zanger UM, Schwab M. Cytochrome P450 enzymes in drug metabolism: regulation of gene expression, enzyme activities, and impact of genetic variation. *Pharmacol Ther*. 2013;138(1):103-141.
- 15 Bakken GV, Molden E, Hermann M. Impact of genetic variability in CYP2D6, CYP3A5, and ABCB1 on serum concentrations of quetiapine and N-desalkylquetiapine in psychiatric patients. *Ther Drug Monit*. 2015;37(2):256-261.
- 16 Bondolfi G, Morel F, Crettol S, Rachid F, Baumann P, Eap CB. Increased clozapine plasma concentrations and side effects induced by smoking cessation in 2 CYP1A2 genotyped patients. *Ther Drug Monit*. 2005;27(4):539-543.
- 17 Zullino DF, Delessert D, Eap CB, Preisig M, Baumann P, Tobacco and cannabis smoking cessation can lead to intoxication with clozapine or olanzapine. *Int Clin Psychopharmacol*. 2002;17(3):141-143.
- 18 Klotz U. Pharmacokinetics and drug metabolism in the elderly. *Drug Metab Rev*. 2009;41(2):67-76.
- 19 Aichhorn W, Weiss U, Marksteiner J, et al. Influence of age and gender on risperidone plasma concentrations. *J Psychopharmacol*. 2005;19(4):395-401.
- 20 Gross AS. Best practice in therapeutic drug monitoring. *Br J Clin Pharmacol*. 2001;52 Suppl 1:5S-10S. Review.
- 21 Pobre MA, Predmore Z, Horvitz-Lennon M, Mattke S. Point of care antipsychotic plasma levels for patients with schizophrenia: cost savings potential in Spain. In: Janssen Pharmaceuticals I, Diagnostics J Health R, eds. *ISPOR 19th Annual European Congress (International Society for Pharmacoeconomics and Outcomes Research)*. 2016.

© 2018 Saladax Biomedical, Inc.

MyCare™ is registered trademark of Saladax Biomedical, Inc.  
116 Research Drive, Bethlehem, PA 18015 U.S.A Tel: +1 610 419-6731  
saladax.com LIT MULT-021 Rev 01

