PGxPredict®:CLOZAPINE

PGxHEALTH • FIVE SCIENCE PARK • NEW HAVEN, CT 06511 • WWW.PGXHEALTH.COM
Customer Service: 1.877.2.PGxHealth (877.274.9432) • Fax: 203.786.3418

Test Requisition

PATIENT INFORMATION

Name: Last ______________________ First ______________________ MI ________

Address: Street ______________________________________ Apt # ________

City ______________________ State ______________ Zip ________

Telephone: Daytime ______________________ Evening ______________________

DOB: MM/DD/YY ______________________ SSN ______________________

☐ Male ☐ Female Ethnicity ______________________

REFERRING PHYSICIAN/ACCOUNT INFORMATION

Name: Last ______________________ First ______________________ Degree ________

Address: Street ______________________________________ Suite # ________

City ______________________ State ______________ Zip ________

Institution/Hospital ______________________________________

Telephone ______________________ Fax ______________________

Email ______________________________________

NPI # ______________________ Group NPI # ______________________

Office Contact ______________________________________

ADDITIONAL PHYSICIAN TO RECEIVE TEST RESULTS

Name: Last ______________________ First ______________________ Degree ________

Address: Street ______________________________________ Suite # ________

City ______________________ State ______________ Zip ________

Institution/Hospital ______________________________________

Telephone ______________________ Fax ______________________

Email ______________________________________

BILLING INFORMATION

BILL: ☐ **Facility Account** ☐ **Patient Insurance** ☐ **Self-pay** ☐ **Medicaid** ☐ **Medicare**

For Facility Accounts
NAME OF FACILITY ACCOUNT ______________________________________

For Patient Insurance
PRIMARY INSURANCE: Please provide a legible copy of the front and back side of the insurance card.

SECONDARY INSURANCE: You may submit secondary insurance information when applicable. Please provide a legible copy of both sides of the insurance card.

☐ Please check box if you'd like PGxHealth to contact the patient (or legal guardian) with insurance benefit information before performing test(s).

Primary Insurance Company ______________________________________

Address: Street ______________________________________

City ______________________ State ______________ Zip ________

Telephone ______________________________________

Policy Holder/Subscriber ______________________________________

Relationship to Patient ______________________________________

Policy Holder's DOB ______________ Policy Holder's SSN ______________

Policy # ______________________________________

Group # (if applicable) ______________________________________

Name of Employer ______________________________________

PATIENT PAYMENT: Mail payments to: PGxHealth, PO Box 83236, Woburn, MA 01813-3236

For Self-pay
PGxHealth accepts the following credit cards: Visa, MasterCard, AMEX and Discover.

☐ Yes, I plan on using my credit card to pay for testing. Please contact me directly.

DIAGNOSIS /ICD-9 CODE(S)

Diagnosis/ICD-9 Code(s) ______________________________________

SUSPECTED CLINICAL/REFERRAL DIAGNOSIS

PGxPredict:CLOZAPINE
☐ Neutropenia ☐ Agranulocytosis ☐ New Drug Prescription

REQUIRED PATIENT/PHYSICIAN SIGNATURES

REQUIRED FOR PATIENT INSURANCE OPTION:

- I acknowledge that I have selected the patient insurance billing option and hereby authorize PGxHealth to bill my insurance carrier. Further, I authorize PGxHealth to disclose to my insurance carrier the information on this form and any accompanying documentation provided by my healthcare provider. I authorize my health plan or insurance carrier, and other third parties involved in the administration of my plan, to disclose to PGxHealth information concerning my plan, including benefits, coverage limitations, and payments made for services.

- I hereby assign and authorize payment directly to PGxHealth of any benefits for the services provided. I understand that my insurance may not cover these services, or may only pay up to usual and customary rates, and that I am ultimately responsible for all costs of this test and costs of collections, including attorney fees, court costs, filing fees, and late payment fees, except where my liability is limited by contract or applicable state or Federal law.

Patient/Responsible Party (REQUIRED FOR PATIENT INSURANCE OPTION)

Signature ______________________ **Date** ______________ Please Sign & Date

PATIENT/RESPONSIBLE PARTY SIGNATURE TO AUTHORIZE TESTING AND VERIFY INFORMED CONSENT (REQUIRED):
I authorize my physician and other medical personnel to provide information to PGxHealth concerning my medical history, and I authorize PGxHealth to disclose the results of my testing and any related health and personal information to my physician. I have read the Informed Consent for PGxPredict:CLOZAPINE testing and understand its contents. I have had the opportunity to ask questions about this form and have had any questions answered.

Patient or Legal Guardian (REQUIRED):

Signature ______________________ **Date** ______________ Please Sign & Date

Print Name ______________________________________

Relationship ______________________________________

PHYSICIAN SIGNATURE TO AUTHORIZE TESTING (REQUIRED):
I certify that the Informed Consent has been signed by the patient or an individual legally authorized to do so on the patient's behalf (and that such form is on file), and that I obtained any other consent from the patient that is required under the laws of my state in order to perform a genetic test on a specimen. (Note: test requests without a signature will not be processed.)

Referring physician to authorize testing (REQUIRED):

Signature ______________________ **Date** ______________ Please Sign & Date

PGx HEALTH®
A DIVISION OF CLINICAL DATA

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Informed Consent for PGxPredict®:CLOZAPINE Testing

I request genetic testing for the presence of genetic variants associated with risk of clozapine-induced agranulocytosis. I have discussed the benefits, risks, and limitations of this testing with a physician and/or a genetic counselor and I have had my questions answered. By signing this form, I give my consent to have my blood sample and relevant clinical information sent to PGxHealth, a subsidiary of Clinical Data, Inc. (PGxHealth), who will perform the test. I also authorize PGxHealth to disclose the test results to authorized testing personnel and my ordering physician(s).

I UNDERSTAND THE FOLLOWING BENEFITS, RISKS, AND LIMITATIONS:

1. While genetic testing is a valuable tool, it may not always give a definite answer about the genetic status of an individual. Genetic testing normally gives precise information; possible sources of error include but are not limited to sample misidentification and sample contamination.

2. In rare circumstances, the laboratory may have difficulties analyzing my sample and a second sample may be requested.

3. I authorize my doctor to forward my blood sample and related clinical information to PGxHealth as necessary for test interpretation.

4. The results of this test may indicate that I am particularly at risk for developing clozapine-induced agranulocytosis. I understand that this test result does not change the need for blood monitoring as indicated by the clozapine prescribing information. Follow-up counseling is available from my physician or I may contact a genetic counselor to address questions I may have regarding the results.

5. My blood and DNA sample will be destroyed no more than 60 days after my test results are final. No tests other than those authorized shall be performed on the sample. If I choose not to have testing performed after PGxHealth receives my sample, I can inform them of that decision and my sample will be destroyed in no more than 60 days.

6. Genetic testing may involve emotional stress. By the end of 2009, the Genetic Information Nondiscrimination Act of 2008 will prohibit health insurance plan and employers from some discrimination based on genetic information, including the results of genetic testing. However, such genetic testing may result in insurance discrimination that is not prohibited by law. If other members of my family have had the same or similar tests, the results of this testing may suggest previously unrecognized biological relationships, such as non-paternity.

7. The results of this test will be treated in the standard medically confidential manner and will be released only to the physician(s) ordering the test or other persons authorized by me in writing unless otherwise required by law.

8. In the unlikely event of physical injury resulting from having my blood sampled for this test, I understand that PGxHealth is not able to offer financial compensation or to absorb the cost of medical treatment.

9. By signing this consent, I give PGxHealth permission to retain the genetic information generated by this test. In the interest of science, summary results from this test may be presented, for example at meetings, in publications, or on the Internet; however, no information that can identify me will ever be disclosed, unless authorized in writing by me or required by law.

10. The results of this test are not intended to be used as the sole means for management decisions. This test was developed and its performance characteristics determined by PGxHealth, LLC. FDA approval is not currently required for clinical use of this test. Validation was done as required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

11. There will be a fee for this genetic testing and I will be responsible for payment after the testing has begun, even if I later decide not to receive results.

NOTE:

Genetic testing on children less than 18 years of age requires that the ordering physician obtain an informed consent from a parent or legal guardian.