

SPECIMEN INFORMATION

(All Fields Required)

Collection Method

In-Office Mobile

Specimen ID :

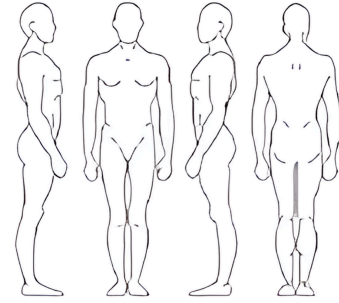
e.g CMA00000

Collection Date : And Time

Collected By :

Patient Type (select one) Switching Biologic Therapy Initial Biologic Therapy

Specimen Collection Location (please circle)



TEST INFORMATION

Mind.Px Test Descriptor

Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics. (CPT Code: 0258U)

ICD-10 CODE (Select all that apply)

- Plaque Psoriasis (L40.0)
 Psoriatic Arthritis (L40.52)
 Other, specify _____

Report Delivery Method

Email _____
 Institutional _____
 Fax _____

Provider Information

Provider Name _____

Provider NPI # _____

Practice Name _____

Practice Address _____

Completion of this section authorizes Mindera Health to release the final test report to the above report delivery method and provider confirms that if using FAX, that device is HIPAA-compliant.

PATIENT INFORMATION

Name

First _____
 Middle _____
 Last _____
 Date of Birth _____

Address

Apartment #/Unit _____ Phone Number _____
 Street _____
 City _____
 State _____ Zip _____

(All required unless otherwise stated)

Optional Sex Male Female

Height (inches) _____ Body Weight (lb) _____

Ethnicity: African-American Asian Hispanic Pacific Islander White Other, Specify _____

INSURANCE INFORMATION

Payment Method Insurance Medicare Self-Pay Direct Client Bill

Attach a copy (front and back) of insurance card(s)

Primary Insurance

Insurance Name _____

Subscriber Name _____
if different from patient

Relationship To Subscriber

Spouse Child Dependent

Subscriber ID # _____

Group # _____

HEALTH PROVIDER CERTIFICATION OF MEDICAL NECESSITY

By signing this form, I, the undersigned (or my duly authorized representative), attest that I am a licensed healthcare professional authorized to order this test and that all information listed above is accurate and complete. I attest that the test is medically necessary and I have fully informed the patient of the details of the test, including the purpose, risks, benefits, limitations of use (*specimen collection manual*), and alternatives as well as the implications of the results, and has been given an opportunity to ask questions and discuss concerns about this test. I confirm that testing is medically necessary for the risk assessment, diagnosis or detection of a disease, illness, impairment, symptom, syndrome, or disorder for the patient. I further attest that I have obtained from the patient all consents and authorizations required by and in compliance with applicable state and federal laws for the performance and billing of the testing being ordered.

- The patient has consented to Mindera Health releasing the test results to the third-party payer (health insurer) when necessary, as part of the reimbursement process, with all benefits of the plan payable directly to Mindera Health.
- The patient has been informed that Mindera Health has the right to appeal on their behalf negative coverage decisions made by the plan and to assert all rights and claims reserved to them as the beneficiary thereof.
- I have informed the patient that he/she may be responsible for amounts not paid by the plan directly to Mindera Health for the test ordered including cost-sharing obligations. Patient has been informed how to obtain a good faith estimate.
- I have informed the patient that this test may not be covered by the patient's plan. If it is outside of the plan's coverage guidelines or deemed not medically necessary (e.g. - where prior authorization is required but not obtained) the patient may be responsible for the cost of the test.
- The patient understands that Mindera Health will contact them to coordinate the receipt and/or delivery of the Mind.Px test and billing inquiries.

Ordering Provider Signature X

Date _____

Informed Consent (For New York & New Jersey Only)

Description of the Mind.Px Test

Mind.Px is a physician-ordered laboratory-developed test intended for use by healthcare professionals to use on individuals who have psoriasis and is not intended to be used for conditions other than psoriasis. Mind.Px and any information provided by the clinical laboratory that analyzes your skin sample are intended for use by healthcare professionals as an aid or an adjunct assay in his/her clinical evaluation of your skin condition, as determined solely by your prescribing healthcare provider, and is not intended for use as a standalone diagnostic test. If you have any questions regarding the Mind.Px test, you should consult with your prescribing healthcare provider. Your healthcare provider will decide if the Mind.Px is medically necessary for you and how they wish to use the information provided by the Mind.Px test in their clinical evaluation. After your healthcare provider orders Mind.Px for you, your provider (or someone under your provider's supervision) will apply the Mindera Health Dermal Biomarker Patch (DBP) to your skin. Your provider will then remove the DBP, which contains a sample of your skin, The DPB is then shipped to Mindera Health's clinical laboratory for biomarker analysis. After analyzing the sample collected by the DBP, the clinical laboratory will then send its report of the results directly to your ordering healthcare provider. The performance characteristics of this test were validated by Mindera Health's clinical laboratory. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The U.S. Food and Drug Administration (FDA) has not approved or cleared this test; however, FDA approval or clearance is currently not required for clinical use of this test.

Risk and Limitations of the Mind.Px test

Although unexpected, there is a slight chance that some patients may experience temporary skin redness or minor skin irritation after applying the DBP. Your healthcare provider can address any concerns you may experience or have about the DBP application and the sample collection steps. There is a chance that the laboratory report provided to your healthcare provider may contain certain errors, including errors due to sample mix-up, poor sample quality or contamination, and technical errors in the laboratory.

Mind.Px Test Results

Due to the complexity and important implications of the test results, Mindera Health sends your test results only to your designated provider(s). You may contact your provider to obtain your test results. Mindera Health maintains the confidentiality of your tests results and health information as required under the Health Insurance Portability and Accountability Act (HIPAA) and applicable state laws. Your provider will evaluate and discuss with you the results of your Mind.Px test, in conjunction with your relevant clinical information in order to determine the best course of treatment for you. Mindera Health does not offer any interpretative findings or evaluations. It is your provider's responsibility to review the test results and provide you with their medical interpretation.

Informed Consent

I understand the benefits, risks, alternatives and limitations associated with the Mind.Px test as well as my right to not use the Mind.Px. I have been sufficiently informed and have had the opportunity to ask questions and discuss concerns about the Mind.Px test with my doctor. I have been informed that I will receive the results of the test once my provider has viewed and interpreted them. I understand that this authorization is voluntary and that Mindera Health will not condition my treatment, payment, enrollment or eligibility for benefits on this authorization. I understand that I may revoke this authorization at any time by sending a written request to Mindera Health at the address above, but that revoking my authorization will not affect any use or disclosure of my information that has already occurred, or action taken in reliance on my authorization. I understand that once my information has been disclosed, U.S. federal privacy laws may no longer apply, and the information may be further disclosed. This authorization will remain valid unless and until I revoke it in writing, or earlier if required by applicable law. I consent to Mindera Health's collection of my health information necessary to perform the test and acknowledge that such information and any information derived from my samples will be retained by Mindera Health indefinitely.

By signing this form, I acknowledge that I have been given adequate time to read this Consent Form. I understand the benefits, risks, alternatives and limitations associated with the Mind.Px test as well as my right to not use the Mind.Px.

Printed Name of Patient / Guardian _____ Date _____

Signature of Patient / Guardian X _____ Date _____

Research Consent (Optional)

If you agree, Mindera Health may de-identify, aggregate, store, and use your sample and the information associated with the sample for educational, internal quality control, validation studies, business, marketing and/or research and development purposes. De-identification means that the Personal Information associated with your biological sample or genetic information will be removed. Information and results in our research may be shared with third party collaborators including government, academic, and commercial entities. We, our collaborators, or partners may author publications using de-identified information, either on our own or in collaboration with third parties. We may disclose, sell and otherwise commercialize de-identified information without restriction. Mindera Health may receive financial compensation to conduct such research using your de-identified information and skin sample. You understand that by providing a sample, having your sample processed, or providing information to Mindera Health, you acquire no rights in any research or commercial products that may be developed by us or our collaborating partners. You will not receive compensation or any rights, including any right to royalty, for any research or commercial products that include, derived from, or result from your sample or information.

PATIENT SIGNATURE

I permit my de-identified sample and information resulting from its analysis to be stored by Mindera Health or its designee for as long as deemed useful, which may be indefinitely, and used by Mindera Health, its affiliates and research partners for future research and development purposes.

Signature of Patient / Guardian X _____ Date _____