



SPECIMEN INFORMATION

Collection Method Provider Mobile

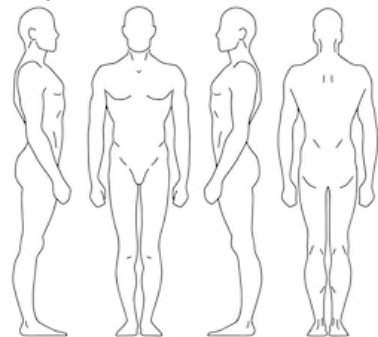
Specimen ID : (Required)

Collection Date : And Time (Required)

Patient Type Required (Select One)

Initial Biologic Therapy Switching Biologic Therapy

Specimen Collection Location



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)

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

PROVIDER INFORMATION

Provider Name Provider NPI # Practice Name Report Delivery Method E-mail Fax

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

(All Required Unless Otherwise Stated)

Name First Middle Last Date of Birth Sex Male Female Height (inches) (optional) Ethnicity: African-American Asian White Hispanic Pacific Islander Other, specify Body Weight (lb) (optional) Address Apartment #/Unit Street City State ZIP

INSURANCE INFORMATION

Attach a copy (Front and Back) of Insurance Card(s)

Payment Method Insurance Medicare Self-Pay Direct Client Bill

Primary Insurance Insurance Name Subscriber Name (if different from patient) Relationship To Subscriber Spouse Child Dependent Other (Specify) 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 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. I confirm the following:

- 1. 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.
- 2. 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.
- 3. 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.
- 4. 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.
- 5. 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 (or Authorized Delegate*)

Date (mm/dd/yyyy)

*Delegate has the authorization to sign supporting form and documents on behalf of the Ordering Provider



Mindera Health Mind.Px Test | Informed Consent

Introduction

This consent form ("Consent") describes the purpose, procedure, possible benefits and risks and limitations of the Mindera Health ("we", "us" or "our") Mind.Px test ("Mind.Px"). This is a voluntary test. You must acknowledge that you have reviewed, understand, and agree to this Consent by signing the bottom of this page. You will be provided with a copy for your records. Throughout this Consent, "you", "your", "me", "my", and "I" refers to the person whose information and sample is being provided for the Mind.Px test.

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 he/she wishes to use the information provided by the Mind.Px test in his/her 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 DBP 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.

Benefits of the Mind.Px Test

The Mind.Px test can provide additional information regarding your response to certain medical treatments for your condition.

Risks 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.

The analysis of your Mind.Px test is based on currently available information. Future scientific research may change the interpretation of your results as the scientific community may show previous information to be incomplete or inaccurate. Your healthcare provider is solely responsible for deciding how to interpret or use the biomarker information provided in the clinical laboratory report after processing your skin sample.

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

Because of 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.

Contacting Mindera Health

If you have questions or comments about our Mind.Px test or this Consent, please contact us at: Mindera Health, 1221 Liberty Way, Vista, CA 92081 / 858.810.6070 / mind.px@minderahealth.com.

INFORMED CONSENT FOR THE MIND.PX & INSURANCE ACKNOWLEDGMENT

By signing below, 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. 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. I have been informed that if my medical insurance does not cover this test, I am financially responsible for the full dollar amount of this test. If I change my mind about the test, a reduced fee refund will be provided for cancellations received after my sample has been collected but prior to Mindera Health performing the test. Once Mindera Health performs the test, no fees can be refunded.

Patient/Guardian signature (Required)

Date

OPTIONAL CONSENT FOR RESEARCH

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.

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: Initial here:

YES

NO

Initials _____

I permit researchers at Mindera Health to contact me or my provider in the future for an update on my status, or to discuss potential research studies or other health-related products or services which may be appropriate for me: Initial here:

YES

NO

Initials _____