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| --- | --- | --- | --- |
| Printed: $[P\_DATE] | $[P\_HOUR] |  |  |
| Patient | $[PATIENT] | **Order Date:** | $[ORDER\_DATE] |
| DOB: | $[DOB] | **Location:** | Life Sciences Testing Center E |
| NUID: | $[NUID] | **Order ID:** | $[ORDER\_ID] |
| Phone: | $[PHONE] | **Ordering Provider:** | Alzheimer, Alois, M.D. |
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| --- | --- | --- |
| DURITECT-ADTM |  |  |
| Final – Approved $[APPROVED\_DATE] | **Sample Type:** Whole Blood | **Sample ID:** $[SAMPLE\_ID] |
| Approved by: $[APPROVED\_BY] |  | **Collected:** $[COLLECTED\_DATE] |

|  |  |
| --- | --- |
| TEST | RESULT |
| DURITECT-ADTM autoantibody panel | **$[RESULT]** |
|  | *$[RESULT\_TEXT]* |

**Disclaimer:** Duritect-AD™ is a Laboratory Developed Test (LDT) designed, validated, and performed under the Clinical Laboratory Improvement Amendments (CLIA) program (CLIA ID: 22D2186779) by the Life Sciences Testing Center of Northeastern University, 147 South Bedford St., Burlington, MA 01803. It is a qualitative multiplexed chemiluminescence immunoassay-based in vitro diagnostic device that measures a panel of 5 antibody signatures detected in serum isolated from peripheral whole blood to generate a single numeric Risk Score. The test is intended to aid in the diagnostic evaluation of adult patients aged 55 and older presenting in primary care settings with signs or symptoms of cognitive impairment that may suggest Alzheimer’s disease (AD) or other causes of cognitive decline. The assay's performance characteristics have been established and validated in accordance with CLIA standards.

This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).

For more information, visit http://durinlifesciences.com.

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| **Reporting Laboratories:** |
| 1. Life Sciences Testing Center (CLIA ID: 22D2186779), Medical Director: Abel, Gyorgy, M.D., 147 South Bedford St, Burlington, M A 01803, (781) 238-8406 |

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| Printed: $[P\_DATE] | $[P\_HOUR] |  |  |
| Patient | $[PATIENT] | **Order Date:** | $[ORDER\_DATE] |
| DOB: | $[DOB] | **Location:** | Life Sciences Testing Center E |
| NUID: | $[NUID] | **Order ID:** | $[ORDER\_ID] |
| Phone: | $[PHONE] | **Ordering Provider:** | Alzheimer, Alois, M.D. |
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**DURITECT-ADTM- Test Result**

DURITECT-ADTM  Alzheimer’s Disease Risk Score: $[RS]

|  |  |  |
| --- | --- | --- |
| **ADRS** | **RESULT** | **REFERENCE INTERVAL** |
| Typical risk of AD pathology | Negative | 0-39.9 |
| Intermediate risk of AD pathology | Intermediate | 40-68.8 |
| Increased risk of AD pathology | Positive | 68.9-100 |

**Comments:** Patients with “positive” test results (“increased risk of AD-related pathology”) have an Alzheimer’s Disease Risk Score (ADRS) indicating a higher likelihood that cognitive impairment symptoms are due to AD and should be referred to additional diagnostic, cognitive, and physiological examinations consistent with professional guidelines for AD diagnosis. Patients with “negative” test results (“Typical risk of AD-related pathology”) have a lower ADRS indicating a lower likelihood that cognitive impairment symptoms are due to AD and should be monitored and evaluated for other conditions that mimic early symptoms of AD, consistent with professional clinical guidelines. Patients with “indeterminate” test results (inconclusive), cannot be definitively interpreted as positive or negative for the increased or decreased risk of the presence of AD-related pathology. Further evaluation may be needed. Please consult your healthcare provider to discuss next steps.

The Duritect-ADTM test is not intended for screening asymptomatic patients, stand-alone diagnostic purposes, or to definitively confirm or exclude a diagnosis of AD or other cognitive conditions. The performance of the ADRS has not been established for predicting development of dementia or other neurologic conditions or for monitoring responses to therapies.

Duritect-AD TM is for prescription use only. Test results should be interpreted by healthcare professionals in conjunction with other clinical assessments and diagnostic tools, consistent with professional standards of clinical practice.

For more information visit <http://durinlifesciences.com>

Approved By: Gyorgy Abel, MD.

Results were obtained by a multiplex Luminex based assay and Machine leaning. More description to follow in this section.

References:

1. Early Detection of Alzheimer's Disease-Related Pathology Using a Multi Disease Diagnostic Platform Employing Autoantibodies as Blood-Based Biomarkers. Journal of Alzheimer's Disease 92 (2023) 1077–1091.

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