A diagnosis of exclusion often results in delayed, missed and misdiagnosis of fibromyalgia.

"Delayed diagnosis increases costs for insurance companies while adding to burden on patients." – AJMC participant

### Annual Cost of Delayed Diagnosis*

<table>
<thead>
<tr>
<th>Total US Population</th>
<th>Total Health Care Utilization: $8.6B</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Testing &amp; Imaging $3.12 Billion</td>
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<tr>
<td></td>
<td>Referrals: $2.02 Billion</td>
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<tr>
<td></td>
<td>GP Visits: $567 million</td>
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<td>Pharmaceuticals: $2.89 Billion</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>US Medicare Population</th>
<th>Total Health Care Utilization: $1.4 B</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Testing &amp; Imaging $514 million</td>
</tr>
<tr>
<td></td>
<td>Referrals: $333 million</td>
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<tr>
<td></td>
<td>GP Visits: $93 million</td>
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<td>Pharmaceuticals: $477 million</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Practice Population** of 3,000 Lives</th>
<th>Total Health Care Utilization: $75,981</th>
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<tbody>
<tr>
<td></td>
<td>Testing &amp; Imaging $27,564</td>
</tr>
<tr>
<td></td>
<td>Referrals: $17,856</td>
</tr>
<tr>
<td></td>
<td>GP Visits: $5,004</td>
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<td></td>
<td>Pharmaceuticals: $25,557</td>
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<table>
<thead>
<tr>
<th>Practice Population** of 100,000 Lives</th>
<th>Total Health Care Utilization: $2,530,167</th>
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<tbody>
<tr>
<td></td>
<td>Testing &amp; Imaging $918,708</td>
</tr>
<tr>
<td></td>
<td>Referrals: $595,140</td>
</tr>
<tr>
<td></td>
<td>GP Visits: $166,783</td>
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<tr>
<td></td>
<td>Pharmaceuticals: $851,814</td>
</tr>
</tbody>
</table>


**Practice Population refers to Total Patient Lives covered with a 5% undiagnosed FM rate. Excludes cost of diagnosis

Providers might be legitimately concerned not only with the costs of diagnosing FM but the costs of not diagnosing FM.*

Patients can spend between $10,000 to $42,500 on testing, imaging and referrals prior-to diagnosis.

“Documented costs of delayed diagnosis are probably even higher in reality, with more advanced disease feeding into higher costs after late diagnosis.

*There are numerous conditions that present with symptoms that are similar to those of fibromyalgia, including hypothyroidism, MS, RA and SLE. It’s important to speak to your doctor to determine if you are at risk for any of these or other conditions.

In some cases, patients treated for a diagnosed disorder such as depression, hypothyroidism, RA, SLE, and MS (as well as other conditions), continue to have fibromyalgia-like symptoms despite their treatment protocols. Absent a diagnostic test for fibromyalgia, these patients may be misdiagnosed as having concurrent fibromyalgia, masking sub-optimal response to the treatment protocol for their primary disorder.


FM/a®® is the first objective laboratory blood test capable of confirming the diagnosis of fibromyalgia (FM). FM patients can receive their test results in one week or less.

FM/a®® is a laboratory developed test (LDT) that was developed at the University of Illinois College of Medicine and is performed by EpicGenetics at their CLIA certified and CAP® accredited laboratory.

Save 98% of the cost to diagnose fibromyalgia

### The first objective test capable of diagnosing Fibromyalgia.

**FM/a®

Confirming the Diagnosis of Fibromyalgia with Advanced Science

Diagnosis made by Rheumatologists confirmed initial diagnosis made by Primary Care physicians in 71% of referrals.®
Fibromyalgia is characterized by widespread musculoskeletal pain, abnormal pain processing, fatigue and psychological distress.

- History of widespread pain occurring on both sides of the body, above and below the waist.
- Symptoms present for at least 3 months.
- Patient does not have a disorder that would otherwise explain the pain.

### Additional Symptoms

- Tenderness to the touch or pressure affecting joints and muscles
- Pain typically observed in 11 of 18 tender points
- Problems with memory: “brain fog”
- Irritable bowel syndrome (IBS)
- Irritable or overactive bladder
- Excercise intolerance
- Migraines
- Depression and anxiety
- Fibromyalgia
- Fatigue
- Hypothyroidism
- Overactive bladder
- Irritable bowel syndrome

### Prevalence

Until recently, the prevalence of fibromyalgia in the U.S. was thought to be approximately 2% of the population (3 million adults), with women affected at a rate of 7:1.

However, a 2012 population-based study utilizing the Rochester Epidemiology Project, projects a prevalence rate of 6.4% of the U.S. population or 20 million - a rate comparable to that of diabetes. Prevalence amongst men was found to be 20x the current diagnosis rate.

While most people are diagnosed with fibromyalgia between 30 and 60 years of age, emerging research indicates that children can also have the disorder.

Only 1.1 million of an estimated 20 million Americans with fibromyalgia have been diagnosed with fibromyalgia.

### Characteristics of Fibromyalgia

#### FM/a® Confirming the Diagnosis of Fibromyalgia with Advanced Science

**FM/a®** is the first objective laboratory blood test capable of confirming the diagnosis of fibromyalgia (FM). FM patients can receive their test results in one week or less.

The innovative multi-biomarker based test utilizes an advanced In Vitro Diagnostic Multivariate Index Array (IVDMI/A) technology to analyze patient white blood cells (PBMCs) and evaluate the expression levels of immune system cytokine and chemokine patterns found to be altered in patients with fibromyalgia®. Values for these biomarkers are combined into a predictive score using a multi-analyte assay with algorithmic analysis (MAAA) technology.

**FM/a®** is a laboratory developed test (LDT) that was developed at the University of Illinois College of Medicine and is performed by EpicGenetics at their CLIA certified and CAP accredited laboratory.

In clinical studies, patients with fibromyalgia have been identified to have significantly dysregulated patterns of immune system cytokine and chemokine expressions as compared to control and other rheumatologic disease populations.

### FM/a® and Comorbid Conditions

Patients with fibromyalgia commonly present with symptoms of depression, anxiety, migraines, IBS and/or TMJ and are often initially diagnosed or misdiagnosed with one or more of these disorders.

These conditions are often resistant to traditional treatments, such as antidepressants, that do not address the underlying fibromyalgia and immune system dysfunction.

**FM/a®** should be used to determine if patients presenting with symptoms of depression, anxiety, migraines, IBS, and/or TMJ are suffering from undiagnosed fibromyalgia as their primary illness, in order to determine the most appropriate treatment and improve the outcomes of these chronic conditions which affect over 100 million people in the US.

### FM/a® Test Results

**Objective, Quantifiable Results**

Test results are based on a 1-100 scoring system, with patients with active disease activity scoring 51 and above.

**Accurate**

The sensitivity for FM/a® is 93+% and its specificity is 89+%.

**Fast**

Test results available in 5-7 days.

*No medical test is 100 percent accurate. FM/a® sensitivity is comparable to the HIV blood test. By comparison, the rheumatoid arthritis blood test is only 50 percent sensitive.

The collection of symptoms that is characteristic of FM is experienced by over 100 million people in the U.S. and make-up 30% of all physician visits.

Symptoms of SLE, RA, CFS, MS, and Hypothyroidism, depression often resemble or mimic those of fibromyalgia.

The FM/a® test can be used to determine whether the observed FM symptoms are a result of concurrent fibromyalgia or are instead indicative of sub-optimal treatment and management of the primary disorder.

Early diagnosis/exclusion of FM can help better target treatment options for these conditions, reducing healthcare costs and improving quality of life, amongst this non-core FM population of over 20 million people in the US.