

## LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1978 45 Y

**Referral Testing** 

Collected: 08/24/2023 15:49 Received: 08/24/2023 15:49

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Tamoxifen and Metabolites, Serum/Plasma

Tamoxifen None Detected ng/mL QCRL

Reporting Limit: 1.0 ng/mL

Synonym(s): Nolvadex(R)

Tamoxifen undergoes demethylation to

N-desmethyltamoxifen and tamoxifen and

 ${\tt N-desmethyltamoxifen} \ {\tt are} \ {\tt hydroxylated} \ {\tt to}$ 

4-hydroxytamoxifen and

4-hydroxy-N-desmethyltamoxifen (endoxifen),

respectively. Tamoxifen is a prodrug; the

pharmacological effects are mediated through its

hydroxylated metabolites.

A dose-concentration relationship has been identified

for tamoxifen.

In patients receiving 1, 5, or 20 mg/day tamoxifen for

28 days, mean (range) plasma tamoxifen

concentrations were:

1 mg/day = 7.5 (2.9-120.9) ng/mL

5 mg/day = 25.2 (1.9-180.9) ng/mL

20 mg/day = 83.6 (8.7-134.4) ng/mL.

Analysis by High Performance Liquid Chromatography/

Tandem Mass Spectrometry (LC-MS/MS)

N-desmethyltamoxifen None Detected ng/mL QCRL

Reporting Limit: 1.0 ng/mL

Synonym(s): Tamoxifen Metabolite

A dose-concentration relationship has been identified

for N-desmethyltamoxifen, an inactive tamoxifen

metabolite.

In patients receiving 1, 5, or 20 mg/day tamoxifen for

28 days, mean (range) plasma N-desmethyltamoxifen

concentrations were:

1 mg/day = 9.9 (1.3-135) ng/mL

5 mg/day = 36.2 (3.6-282.2) ng/mL

20 mg/day = 112.3 (14.3-211.6) ng/mL

Analysis by High Performance Liquid Chromatography/

Tandem Mass Spectrometry (LC-MS/MS)

Endoxifen None Detected ng/mL QCRL

Reporting Limit: 1.0 ng/mL

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL,  $\,$  . - NOT TESTED

F224000028 WX0000003827 Printed D&T: 08/24/23 15:49 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 3



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Synonym(s): 4-Hydroxy-N-desmethyltamoxifen; Tamoxifen Metabolite

Hydroxylation of N-desmethyltamoxifen to endoxifen, an active tamoxifen metabolite, is catalyzed by CYP2D6 and genetic polymorphisms which result in low CYP2D6 activity (poor metabolizers) or co-administration of drugs which inhibit CYP2D6 can greatly reduce plasma concentrations of endoxifen reducing the overall efficacy of tamoxifen.

efficacy of tamoxifen. Women receiving 30 mg tamoxifen/day for 10-112 (average = 42) days had a mean (range) endoxifen plasma concentration of 8.6 +/- 7.0 (3.0 - 28.0) ng/mL. In one study, patients taking a CYP2D6 inhibitor along with 20 mg/day tamoxifen for four months had mean plasma endoxifen concentrations of 14.8 +/- 10.6 as compared to patients taking only tamoxifen (mean plasma concentration = 26.7 +/- 15.4 ng/mL). In comparison, CYP2D6 poor metabolizers had mean plasma endoxifen concentrations of 7.2 +/- 2.3 ng/mL.

Analysis by High Performance Liquid Chromatography/ Tandem Mass Spectrometry (LC-MS/MS)

4-Hydroxy-Tamoxifen None Detected ng/mL QCRL

Reporting Limit: 1.0 ng/mL

Synonym(s): Tamoxifen Metabolite A dose-concentration relationship has been identified for 4-hydroxytamoxifen, an active tamoxifen metabolite. In patients receiving 1, 5, or 20 mg/day tamoxifen for 28 days, mean (range) plasma 4-hydroxytamoxifen concentrations were:

1 mg/day = 0.6 (0.4-6.0) ng/mL5 mg/day = 1.3 (0.4-5.9) ng/mL20 mg/day = 3.1 (0.4-7.3) ng/mL

Hydroxylation of tamoxifen to 4-hydroxytamoxifen is catalyzed by CYP2D6 and genetic polymorphisms which result in low CYP2D6 activity (poor metabolizers) or co-administration of drugs which inhibit CYP2D6 can greatly reduce plasma concentrations of 4-hydroxytamoxifen reducing the overall efficacy of

4-hydroxytamoxifen reducing the overall efficacy of tamoxifen.

Analysis by High Performance Liquid Chromatography/ Tandem Mass Spectrometry (LC-MS/MS) This test was developed and its performance characteristics determined by NMS Labs. It has not

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Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 3



## LABORATORY REPORT

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Test Name Result Flag Ref-Ranges Units Site

been cleared or approved by the US Food and Drug Administration. Test Performed at: NMS Labs 200 Welsh Rd.

Performing Site:

QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

**Reported Date:** 2023.08.24 15:49 TAMOX

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL,  $\,$  . - NOT TESTED

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