

Overview

Useful For

Monitoring serum hydroxychloroquine concentrations, assessing compliance, and adjusting dosage in patients

Method Name

Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS)

NY State Available

Yes

Specimen

Specimen Type

Serum Red

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Collection Container/Tube: Red top (gel tubes/SST are **not acceptable**)

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. Collect specimen immediately before next scheduled dose.
2. Within 2 hours of collection, centrifuge, and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send a [Therapeutics Test Request](#) (T831) with the specimen.

Specimen Minimum Volume

0.5 mL

Reject Due To

| | |
|-----------------|----|
| Gross hemolysis | OK |
| Gross lipemia | OK |
| Gross icterus | OK |

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|-------------|------|-------------------|
|---------------|-------------|------|-------------------|

| | | | |
|-----------|--------------------------|---------|--|
| Serum Red | Refrigerated (preferred) | 28 days | |
| | Frozen | 28 days | |
| | Ambient | 21 days | |

Clinical & Interpretive

Clinical Information

Hydroxychloroquine is an antimalarial drug used to treat or prevent malaria. It is highly effective against erythrocytic forms of *Plasmodium* but not effective against exoerythrocytic forms of parasites. Hydroxychloroquine is also used to treat symptoms of acute or chronic rheumatoid arthritis and systemic lupus erythematosus (SLE).

Adult doses range from 400 mg/week for suppressive therapy to 1200 mg/day for acute malaria attacks. Typical daily doses of 200 to 600 mg are used for SLE and rheumatoid diseases. Hydroxychloroquine has a long terminal elimination half-life in blood (>40 days), which exceeds that in serum. The oral bioavailability averages 75%.

Hydroxychloroquine accumulates in several organs, especially melanin-containing retina and skin. Mild to moderate overdose can result in gastrointestinal tract effects (ie, nausea, vomiting, and abdominal pain), headache, visual and hearing disturbances, and neuromuscular excitability. Acute hepatitis, cardiotoxicity, and retinopathy may occur with therapeutic doses. The effects of overdosage with hydroxychloroquine include headache, drowsiness, visual disturbances, convulsions, cardiovascular collapse, and respiratory arrest. Toxic retinopathy has also been associated with higher doses and longer duration of use.

Reference Values

For suppressive treatment of malaria, suggested plasma or serum concentrations should be >10 ng/mL.

For systemic lupus erythematosus, proposed serum target concentrations should be > or =500 ng/mL.

Interpretation

The serum concentration should be interpreted in the context of the patient's clinical response and may provide useful information in patients showing poor response, noncompliance, or adverse effects. Concentrations less than 106 ng/mL have been associated with noncompliance.

Cautions

Specimens that are obtained from serum gel tubes are not acceptable, as the drug can absorb on the gel and lead to falsely decreased concentrations.

Hydroxychloroquine is currently under investigational use for the prevention or postexposure prophylaxis and treatment of COVID-19; the safety and efficacy of its use have not been established.

Clinical Reference

- McChesney EW, McAuliff JP: Laboratory studies on the 4-aminoquinoline antimalarials: II. Plasma levels of chloroquine and hydroxychloroquine in man after various oral dosage regimens. *Antibiot Chemother (Northfield)*. 1962;12(9):583-594
- Mok CC, Penn HJ, Chan KL, Tse SM, Langman LJ, Jannetto PJ. Hydroxychloroquine serum concentrations and flares of systemic lupus erythematosus: A longitudinal cohort analysis. *Arthritis Care Res*. 2016;68(9):1295-1302.

doi:10.1002/acr.22837

3. Durcan L, Clarke WA, Magder LS, Petri M. Hydroxychloroquine blood levels in systemic lupus erythematosus: clarifying dosing controversies and improving adherence. *J Rheumatol*. 2015;42(11):2092-2097. doi:10.3899/jrheum.150379
4. Blanchet B, Jallouli M, Allard M, et al. Whole blood versus serum hydroxychloroquine levels for drug monitoring of patients with systemic lupus erythematosus: preliminary results of a pharmacological study. *Ann Rheum Dis*. 2019;78(2):1168-1169. Abstract SAT0188
5. Soichot M, Megarbane B, Houze P, et al. Development, validation and clinical application of a LC-MS/MS method for the simultaneous quantification of hydroxychloroquine and its active metabolites in human whole blood. *J Pharm Biomed Anal*. 2014;100:131-137. doi:10.1016/j.jpba.2014.07.009
6. Wang LZ, Ong RYL, Chin TM, et al. Method development and validation for rapid quantification of hydroxychloroquine in human blood using liquid chromatography-tandem mass spectrometry. *J Pharm Biomed Anal*. 2012;61:86-92. doi:10.1016/j.jpba.2011.11.034
7. Disposition of Toxic Drugs and Chemicals in Man. 10th ed. Biomedical Publications; 2014
8. Tett SE, Cutler DJ, Day RO, Brown KF. A dose-ranging study of the pharmacokinetics of hydroxy-chloroquine following intravenous administration to healthy volunteers. *Brit J Clin Pharmacol*. 1988;26(3):303-313
9. Gautret P, Lagier JC, Parola P, et al. Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial. *Int J Antimicrob Agents*. 2020;56(1):105949. doi:10.1016/j.ijantimicag.2020.105949
10. Kim SH: Comparison of lopinavir/ritonavir or hydroxychloroquine in patients with mild coronavirus disease (COVID-19). US National Library of Medicine (NLM). 2020. Accessed April 23, 2024. Available at clinicaltrials.gov/ct2/show/NCT04307693
11. Lu H: Efficacy and safety of hydroxychloroquine for treatment of pneumonia caused by 2019-nCoV (HC-nCoV). US National Library of Medicine (NLM). 2020. Accessed April 23, 2024. Available at clinicaltrials.gov/ct2/show/NCT04261517
12. Post-exposure prophylaxis for SARS-coronavirus-2. US National Library of Medicine (NLM). 2020. Accessed April 23, 2024. Available at clinicaltrials.gov/ct2/show/NCT04308668

Performance

Method Description

Samples are extracted with analyte detection by tandem mass spectrometry.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

3 to 7 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

80220

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|-----------------------|--------------------|
| HCQ | Hydroxychloroquine, S | 3684-8 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|-----------------------|---------------------|
| 64947 | Hydroxychloroquine, S | 3684-8 |