Sofia®

QUIDEL

hCG FIA

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the Sofia hCG FIA?
The suggested CPT code is 84703.* The Medicare National Limit amount** is $8.36.

What sample types are approved for use with the Sofia hCG FIA kit?
Urine is the only approved sample type with this kit. Serum or plasma samples are not to be used.

What is the CLIA status of this kit?
This test is CLIA moderately complex.

What is the sensitivity level of the test?
The Sofia hCG FIA yields 100% positive results at 20 mIU/mL.

Can the Sofia hCG FIA be visually interpreted without Sofia?
No, the fluorescence-based chemistry is not detectable without Sofia. Do not try to interpret the results without proper use of Sofia. This is an important feature and ensures objectivity.

Can the Sofia hCG FIA be run in both WALK AWAY and READ NOW modes?
No, the Sofia hCG FIA is designed to be run promptly in WALK AWAY mode. The user should place the Cassette in Sofia after depositing the urine sample. When the drawer is closed, the test will develop and results will automatically be reported in 3 minutes.

What is Kinetic Check™?
Current visual lateral flow-based assays continue to develop over time. For hCG assays, where low level detection can lead to false positive results, it is important to interpret the results at a precise time. Kinetic Check is a proprietary feature within the Sofia system which gives the operator greater flexibility, up to 5 minutes, before placing the Test Cassette into Sofia for analysis. Additionally, if a Test Cassette is allowed to overdevelop, Kinetic Check may cause a Test Cassette to yield an invalid result thereby preventing interpretation of the Test Cassette.

What are Quidel's recommendations for external quality control and calibration testing for this kit?
It is recommended that controls be tested once for each new lot, new shipment of kits, and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements. For information on how to obtain external controls, contact Quidel Technical Support.

The Calibration Check Procedure should be performed every 30 days. Refer to the Sofia User Manual for calibration instructions. If the Calibration Check does not perform as expected, contact Quidel Technical Support. External controls may be used to demonstrate that the reagents and assay procedure perform properly.

What is the shelf life from date of manufacture of the Sofia hCG FIA kit?
How should the kits be stored?
The Sofia hCG FIA kit has a shelf life of 18 months from date of manufacture and should be stored at room temperature (15°C to 30°C, 59°F to 86°F).

How soon after conception does your product detect pregnancy?
Specimens containing as low as 20 mIU/mL hCG for urine will yield positive results when tested with Sofia hCG FIA. In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32-48 hours, peaking in excess of 100,000 mIU/mL in approximately 10-12 weeks.[1] For some patients, an hCG level of 25 mIU/mL can be detected as early as 2-3 days before expected menses.[2]

How long after delivery, spontaneous abortion (estimated to occur in up to 31% of pregnancies overall),[3] or hCG injections will hCG remain detectable in the patient sample?
hCG may remain detectable for a few days to 2 months after these events, depending upon the starting level of hCG.

Are there any diagnosis/conditions in which a patient may not have a normal pregnancy but produce a positive test result?
Ectopic pregnancy, undiagnosed (sub-clinical) abortion, spontaneous abortion, blighted ovum, patients with trophoblastic and non-trophoblastic disease may have elevated hCG levels.[4] The possibility of hCG secreting neoplasms should be eliminated prior to the diagnosis of pregnancy. In addition, serum of postmenopausal women may also contain low-levels of hCG.[5]

How does the beta subunit of hCG affect the test?
The Sofia hCG FIA uses monoclonal antibodies specific to the beta subunit of hCG to capture and detect hCG. The beta subunit was chosen to ensure high specificity of the assay as the alpha subunit of hCG is nearly identical to the alpha subunit found in LH, FSH and TSH.

Can dilute urine (specific gravity of less than 1.007) produce a false negative result?
If the urine is very dilute and has a low specific gravity, the sample may not contain representative urinary hCG concentrations and may fall below the detection level of our test. If this is suspected, it is suggested that another sample be used, ideally first morning void. Significant variation of hCG in serum vs. urine may occur due to diurnal variation. If it is not medically advisable to postpone testing, it is advisable to perform a beta quantitative test.[6]

What volume of patient sample is dispensed by the Fixed-Volume Pipettes included in the Sofia hCG FIA kit?
Approximately 120 µL.

Refer to the Package Insert on our website at **quidel.com** for additional performance claims.

Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

**For state by state fee schedule go to www.cms.gov.

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[3] Wilcox A.J., Weinberg C.R., O'Connor J.F., Baird D.D., Schlatterer J.P., Canfled R.E.. Armstrong E.G., Nisula B.C. Incidence of Early Loss of Pregnancy, N Eng J Med 319: 189-194 (1988).
[4] Saxena B.B., Endocrinology of Pregnancy, 3rd ed., Fuchs F., Klopper A., Eds., Harper and Row, Philadelphia, PA, 1983; 50-72.
Krieg A.F., In Clinical Diagnosis and Management by Laboratory Methods, Vol. 1, 16th ed., Henry J.B., Ed., W.B. Saunders Co., Philadelphia, 1979, pp 680-692.
Wide L., Gemzell C.A. Acta Endocrinol., 35:261-267 (1960).
[5] Cole L.A., Khanlian S.A., Muller, C.Y., American Journal of OB/GYN: 275-278, (2008).
[6] Sanford, T., Clinical Diagnosis by Laboratory Methods. 14th Ed. P. 43.