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– **Urgent Field Safety Notice:**

CLINITEK Novus® Automated Urine Chemistry Analyzer

CLINITEK Novus PRO 12 Urinalysis Cassette Instruction for Use with Missing/Incomplete Limitations

To whom it may concern,

Our records indicate that your facility may have received the following products:

Table 1. Affected Products

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)	Lot Number
CLINITEK Novus PRO 12 Urinalysis Cassette	10634644	00630414602660	All In-Date Lots
CLINITEK Novus PRO 12 Urinalysis Cassette - Japan	10697848	00630414591582	All In-Date Lots

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the documentation for the products indicated in **Table 1** above and provide instructions on actions that your laboratory must take.
Siemens Healthcare Diagnostics Inc. has confirmed that two analyte limitations were omitted and nine analyte limitations were incomplete from the Limitation section of the CLINITEK Novus PRO 12 Urinalysis Cassette Instructions for Use (IFU). The summary of these analytes' limitations is provided in **Table 2** below. The limitation information for pH and color are not impacted.

Table 2. **CLINITEK Novus PRO 12 Urinalysis Cassette Limitations for the 11 Affected Analytes**

Albumin	False positive results may occur with the presence of, chlorhexidine, chloroquine, meropenem, or quinidine. The presence of hemoglobin (5 mg/dL or 0.05 g/L) may cause elevated results. False negative results may occur if boric acid, cimetidine (Tagamet), curcuma, hypochlorite, penicillin, Pyridium, potassium chloride, or riboflavin is present
Bilirubin	Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or positive reading. Metabolites of etodolac (Lodine) may cause false positive or atypical results. Atypical colors may indicate the presence of bile pigment abnormalities and the urine specimen should be tested further. The presence of ρ-aminosalicylic acid may give a false positive result. A false negative may occur in the presence of acetylcysteine, ascorbic acid, boric acid, hypochlorite, captopril, mesna, nitrite, curcuma, citric acid, chlorhexidine, or oxalic acid.
Blood	Captopril (Capoten) and other compounds containing sulfhydryl groups may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. False negative results may be obtained in the presence of acetylcysteine, ascorbic acid, formalin, quinidine, cefoxitin, levodopa, mesna, Keflin, curcuma, Lodine, hydrochlorothiazide, metformin, chlorhexidine, or chloroquine.
Creatinine	False positive results may occur with the presence of boric acid, curcuma, glycine, hypochlorite, nitrofurantoin, potassium chloride, or sulfamethoxazole. Urine containing blood (5 mg/dL or 0.05 g/L hemoglobin) or the presence of cimetidine (Tagamet) may cause falsely elevated results. False negative results may occur if captopril, chlorhexidine, formalin, or Lodine is present.
Glucose	Urine samples with a pH of 9.0 and greater will cause falsely elevated glucose results. False positive results may occur in the presence of hypochlorite. A false negative result may occur in the presence of acetylcysteine, ascorbic acid, captopril, mesna, or curcuma.
Ketones	False Trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds that contain sulfhydryl groups, such as mesna (2-mercaptoethane sulfonic acid) and captopril, as well as acetylcysteine, curcuma, formalin, imipenem, or hydrochlorothiazide may cause false positive results or an atypical color reaction. False negative results may occur in the presence of boric acid, formalin, hypochlorite, meropenem, or Lodine.
Leukocytes	Elevated glucose concentrations (≥ 3 g/dL or 160 mmol/L) may cause decreased test results. False negative results may occur in the presence of quinidine, boric acid, Tagamet, glycine, chloroquine, sulfamethoxazole, chlorhexidine, nitrofurantoin, Lodine, hypochlorite, glyburide, or calcium chloride. The presence of cephalexin (Keflex), cephalothin (Keflin), or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge or the presence of formalin or curcuma. High specific gravity may cause falsely lowered leukocyte results.
Nitrite	A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathological microbes or ascorbic acid, Lodine, formalin, chlorhexidine, or oxalic acid. The presence of curcuma or colored precipitates may cause a false positive result.
Protein	False positive results may be obtained with highly buffered or alkaline urine or in the presence of quinidine, chlorhexidine, chloroquine, Pyridium, or Lodine (etodolac). The presence of hemoglobin (≥ 5 mg/dL or 0.05 g/L) may cause elevated results. False negative results may occur if curcuma or hypochlorite is present.

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Specific Gravity	Measurement of specific gravity by refractometry may be influenced by high levels of urinary glucose and protein which can cause underestimation of the actual specific gravity.
Urobilinogen	The reagent area may react with interfering substances known to react with Ehrlich's reagent, such as ρ-aminosalicylic acid and sulfonamides. False negative results may be obtained if formalin, acetylcysteine, captopril, hypochlorite, mesna, Tagamet, curcuma, Lodine, sulfamethoxazole, chlorhexidine, glucose, hydrochlorothiazide, lactose, meropenem, or nitrofurantoin is present. The test is not a reliable method for the detection of porphobilinogen.

This is a labeling issue only. The instrument and cassette work as intended.
Siemens Healthineers is aware of one customer complaint related to this issue. There have been no reports of adverse events.

Risk to Health

The labeling error poses a negligible risk to health. In a worst-case scenario (unexpected or unexplained or incorrect urinalysis test result caused by presence of an unlisted interferent), there could be additional non-invasive testing performed. Siemens Healthineers is not recommending retrospective review of test results because urinalysis test results are normally used to make clinical decisions at the time that the results are reported. Please consult with your Medical Director for further guidance.

Actions to be Taken by the Customer

- Please use Table 2 above in lieu of your current CLINITEK Novus PRO 12 Urinalysis Cassette IFU Limitations section for those 11 affected analytes' limitations.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Siemens Healthineers will be revising the IFU for CLINITEK Novus® PRO 12 Urinalysis Cassette to include the missing and incomplete interferent information in the Limitations section in revision G. Once revised, the IFU revision G be available in Siemens Healthineers Document Library.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Electronically signed by: Roland Ertl
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Date: Sep 19, 2022 12:39 GMT+2

i.A. Roland Ertl, MA

Electronically signed by: THOMAS HUFNAGL
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