

Urgent Field Safety Notice

29155 Rev. B

2012-11

Urine Chemistry Controls

Effect of Temperature on CLINITEK Atlas® and Chek-Stix® Positive Urinalysis Control Solutions

Our records indicate that you were shipped one or more Siemens urinalysis control products, CLINITEK Atlas® Positive Controls, Chek-Stix® Combo Pak, and Chek-Stix® Positive Control.

Product Name	Part Number	SMN	Carton Lot #	Bottle Lot #
Chek-Stix Positive Control	1360	10310482	S9093061B	P9093061B
Chek-Stix Positive Control	1360	10310482	S9094081B	P9094081B
Chek-Stix Positive Control	1360	10310482	S0097091B	P0097091B
Chek-Stix Positive Control	1360	10310482	S0100101C	P0100101C
Chek-Stix Positive Control	1360	10310482	S0103042F	P0103042F
Chek-Stix Positive Control	1360	10310482	S0106062B	P0106062B
Chek-Stix Positive Control	1360	10310482	S9101022D	P9101022D
Chek-Stix Positive Control	1360	10310482	S9105052B	P9105052B
Chek-Stix Positive Control	1360	10310482	S9108092A	P9108092A
Chek-Stix Combo Pak	1364	10310483	C9093061C	P9093061C
Chek-Stix Combo Pak	1364	10310483	C9094081J	P9094081J
Chek-Stix Combo Pak	1364	10310483	C0096091F	P0100101D
Chek-Stix Combo Pak	1364	10310483	C0097091E	P0097091E
Chek-Stix Combo Pak	1364	10310483	C0098101F	P9101022E
Chek-Stix Combo Pak	1364	10310483	C0099091D	P0099091D
Chek-Stix Combo Pak	1364	10310483	C0100101E	P0100101E
Chek-Stix Combo Pak	1364	10310483	C0102012B	P9101022H
Chek-Stix Combo Pak	1364	10310483	C0102012D	P9101022J
Chek-Stix Combo Pak	1364	10310483	C0103042B	P0103042B
Chek-Stix Combo Pak	1364	10310483	C0103042G	P0103042G

Siemens Healthcare Diagnostics Inc.

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Tarrytown, NY 10591

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Effect of Temperature on CLINITEK Atlas and Chek-Stix Positive Urinalysis Control Solutions

Product Name	Part Number	SMN	Carton Lot #	Bottle Lot #
Chek-Stix Combo Pak	1364	10310483	C0106062D	P0106062D
Chek-Stix Combo Pak	1364	10310483	C9105052C	P9105052C
CLINITEK Atlas Positive Control	5019	10311124	S9093061A	P9093061A
CLINITEK Atlas Positive Control	5019	10311124	S9094081A	P9094081A
CLINITEK Atlas Positive Control	5019	10311124	S0097091C	P0097091C
CLINITEK Atlas Positive Control	5019	10311124	S0100101B	P0100101B
CLINITEK Atlas Positive Control	5019	10311124	S0103042A	P0103042A
CLINITEK Atlas Positive Control	5019	10311124	S0103042H	P0103042H
CLINITEK Atlas Positive Control	5019	10311124	S0106062A	P0106062A
CLINITEK Atlas Positive Control	5019	10311124	S9101022A	P9101022A
CLINITEK Atlas Positive Control	5019	10311124	S9101022B	P9101022B
CLINITEK Atlas Positive Control	5019	10311124	S9105052A	P9105052A
Chek-Stix Combo Pak	1364M	10316287	C0099091B	P0099091B
Chek-Stix Combo Pak	1364M	10316287	C0100101G	P0100101G
Chek-Stix Combo Pak	1364M	10316287	C0103042E	P0103042E
Chek-Stix Combo Pak	1364N	10318290	C0099091A	P0099091A
Chek-Stix Combo Pak	1364N	10318290	C0100101H	P0100101H
Chek-Stix Combo Pak	1364N	10318290	C0103042C	P0103042C
Chek-Stix Combo Pak	1364E	10325654	C0099091C	P0099091C
Chek-Stix Combo Pak	1364E	10325654	C0100101F	P0100101F
Chek-Stix Combo Pak	1364E	10325654	C0102012C	P9101022I
Chek-Stix Combo Pak	1364E	10325654	C0103042D	P0103042D
Chek-Stix Combo Pak	1364E	10325654	C0106062E	P0106062E
Chek-Stix Positive Control	1360L	10331652	S9094081C	P9094081C
Chek-Stix Positive Control	1360L	10331652	S0100101A	P0100101A
Chek-Stix Positive Control	1360L	10331652	S9101022C	P9101022C

When these lots of control material are reconstituted, the positive control solution leukocyte result may become negative if the solution is held for more than two hours above 25°C (77°F).

You can use the reconstituted positive control solution for up to eight hours if the solution is held at 25°C (77°F) or lower. If the operating temperature is greater than 25°C and lower than 30°C (77°F and 86°F), the solution can be used for up to two hours.

Effect of Temperature on CLINITEK Atlas and Chek-Stix Positive Urinalysis Control Solutions

This information applies when using the control products with all CLINITEK instruments and when reading the urinalysis strips visually.

There is no risk to health. It is not necessary to review previous test results or to repeat testing.

We apologize for any inconvenience and appreciate your patience while we work to correct this issue.