



Sygehus Syd Slagelse
Klinisk Mikrobiologisk afd.
Ingemannsvej 18
4200 Slagelse

SSI Diagnostica
Vor ref.

13. oktober 2014

Urgent Field Safety Notice

Dermatofyt PCR-kit FSCA 13-10-2014 (01-2014) Tilbagekaldelse af Dermatofyt PCR-kit lot DERM-S

ATT.: Majbritt Eriksen

SSI Diagnostica tilbagekalder hermed Dermatofyt PCR kit, lot no. DERM-S. Årsagen til tilbagetrækningen er, at den interne plasmid-kontrol i primermixet i nogle PCR kørsler ikke opformeres. Sådanne prøver bliver derfor inkonklusive.

PCR test af den plasmid-stock, som blev anvendt til intern kontrol i primermixet ved fremstilling af DERM-S, har vist, at plasmidet var ustabil på trods af opbevaring ved -20 grader Celcius. Denne ustabilitet blev ikke opdaget i vores QC tjek.

Da Dermatofyt PCR'en er en multiplex PCR, er der konkurrence mellem de tre fragmenter som kan amplificeres i kittet (intern kontrol, pan-derm og *T. rubrum* fragment). En reduktion af mængden af amplifiseret intern kontrol fragment vil medføre en højere specificitet af amplifikationen af *T. rubrum* og pan-derm fragmenter, og vice versa.

Kombinationen af ustabil plasmid stock og målsætningen om, at få den højeste specificitet, resulterede i produktionen af et lot, hvor plasmid koncentrationen var under grænsen, hvilket resulterede i, at der i nogen test var en fin amplifikation af den interne kontrol og i andre test, var der ingen amplifikation af den interne kontrol.

Positive test resultater opnået med dette lot er valide, men negative prøver kan være inkonklusive, som følge af, at der ikke er nogen amplifikations produkter overhovedet.

Vil I være så venlige, at kasserer det defekte Dermatofyte PCR lot DERM S, som aftalt med Pernille Olsen fra SSI Diagnostica.

I vil modtage et erstatnings lot eller en kreditnota, som aftalt tidligere.



Med venlig hilsen

Jytte Jørgensen

Jytte Jørgensen, Kvalitetskoordinator

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SSI Diagnostica
Our ref:

13 October 2014

Urgent Field Safety Notice

Dermatophyt PCR-kit FSCA 13-10-2014 (01-2014) Recall of Dermatophyt PCR-kit lot DERM-S

ATT.: Monica R. Roos

SSI Diagnostica hereby recalls Dermatophyt PCR kit, lot no. DERM S

The reason for the recall is that the internal plasmid control in the primer mix in some PCR test is not amplified. Such tests are inconclusive.

PCR test of the plasmid stock, used for internal control in the primer mix in DERM-S shows that the plasmid was unstable when stored at -20 degree Celcius. The instability was not observed in our QC check.

As the dermatophyte PCR is a multiplex PCR there is competition between the three possible fragments amplified (internal control, pan-derm and *T. rubrum* fragment). A decrease in the amounts of amplified internal control fragment will lead to a higher specificity for the amplification of *T. rubrum* and pan-derm fragments, and vice versa.

The combination between the unstable plasmid stock and the aim of getting the highest specificity resulted in production of a lot where the plasmid concentration was below the limit, resulting in fine amplification of the internal plasmid in some cases but absolutely no internal control in other cases.

The positive results obtained with this lot are valid, but negative samples may be inconclusive due to the lack the internal control fragment.

SSI Diagnostica would like you to dispose of the faulty Dermatophyte PCR lot DERM S.

You will receive a replacement lot or a credit note as agreed upon in the earlier phone or mail contact.

This notice needs to be passed on to all those who need to be aware within your organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.



Yours sincerely,

Jytte Jørgensen

Jytte Jørgensen, QA/RA manager

Tel: +45 48299124

jjj@ssi.dk



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SSI Diagnostica
Our ref:

13 October 2014

Urgent Field Safety Notice

Dermatophyt PCR-kit
FSCA 13-10-2014 (01-2014)
Recall of Dermatophyt PCR-kit lot DERM-S

ATT.: To whom it may concern

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The reason for the recall is that the internal plasmide control in the primer mix in some PCR test is not amplified. Such tests are inconclusive.

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Yours sincerely,

Jytte Jørgensen

Jytte Jørgensen, QARA manager

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