**INNLEDNING**

**Enhet, faggruppe:**

**Medisinsk biokjemi, Sykehuset Levanger, Faggruppe 4**

**Parameter:**

**Urinstiks;** spesifikk vekt, pH, leukocytter, nitritt, protein, glukose, ketoner, urobilinogen, bilirubin og blod i urin.

**Prøvematerialer:**

**Urinprøver**

**Metode:**

Semikvantitativ bestemmelse av spesifikk vekt, pH, leukocytter, nitritt, protein, glukose, ketoner, urobilinogen, bilirubin og blod i urin.  
Analyseresultatene er basert på måling av fargeutvikling på strimmel ved hjelp avrefleksjonsfotometri.

**Metodemodifikasjoner vi ønsker å bruke:**

Det er kjøpt en nyere utgave av de gamle instrumentene, med samme måleprinsipp.

**Instrument:**

2 instrument av type Cobas u 411, 13271 med.biokjemi og 13272 prøvetakingslab.

**Referanser:**

1. ALM-; validering av metoder og utstyr EQSDocument 2947 v1.8.
2. Roche Diagnostica; Brukermanual for cobas u 411 Desember 2010 v 2.0
3. Pakningsvedlegg Combur10-Test M 05868998001 (01) 2010-06
4. Pakningsvedlegg Control Test M 05868971001 (01) 2010-05
5. Pakningsvedlegg Liquichek Urinanalysis Control 5258 2012-01

**Ekstern validering:**

Validering utført av Roche Diagnostica mellom Miditron M og cobas u411. Se pakningsvedlegg Combur10-Test M **2**.

**Godkjenninger:**

Instrument, kontroller og kalibreringstrimler er CE-merket etter IVD-direktivet**2**.

**Vedlegg til valideringa:**

Vedlegg 1: Roche Diagnostica; Brukermanual for Cobas u 411

Vedlegg 2: Pakningsvedlegg Combur10-Test M 05868998001 (01) 2010-06

Vedlegg 3: Pakningsvedlegg Control Test M 05868971001 (01) 2010-05

Vedlegg 4: Pakningsvedlegg Liquichek Urinanalysis Control 5258 2012-01

# VALIDERINGSPLAN

## 

## Årsak til validering:

Det er anskaffet to nye instrument, cobas u411.

## Årsak til begrenset validering.

De er en nyere utgave av vårt nåværende instrumet med samme måleprinsipp, reagens, kontroll og standarder.

Vi vil sammenligne de nye instrumentene mot det gamle for å se om de gir samme resultat.

## Klinisk nytteverdi

## Standardisert analysering, avlesning og instrument koblet online med vårt datasystem gir korrekte svar

raskt. Dette gir våre rekvirenter korrekte svar raskt for hjelp i deres diagnostisering.

## Praktisk egnethet

## Våre nåværende instrument er gamle og leverandør kan ikke skaffe viktige deler. Av den grunn er det nødvendig med nye instrument. Sykehuset Namsos har anskaffet og tatt i bruk samme type instrument.

## Klinisk nytteverdi og praktisk egnethet er vurdert som tilfredstillende

Dato: 28.08.2013 Sign: Eva Tingstad

### Bedømmelse av faktorene som innvirker på resultatet

**Kvalitetskontroll:**

### Det skal analyseres Liquichek urinanalysis i to nivå, level 1 og level 2 i ca. 20 dager i innkjøringsperioden for de nye instrumenene.

**Krav:**

Analysesvarene må samsvare med resultat som er oppgitt som fasit for kvalitetskontrollene.

### Pasientprøver:

Det skal analyseres min. 10 pasientprøver med forskjellige utslag.

**Krav:**

Resultatene skal samsvare slik at det blir samme konklusjon på gammelt og nye instrument, + 1 ved avlesning på instrumentene. Vi ønsker 90% samsvar mellom gammelt og nye instrument for hver analytt, kun 1 av 10 med + 1 avvik.

### 

### 

### Andre mål som vi ønsker å måle selv og de metodene vi planlegger å bruke

### Analytisk kvalitet

#### Repeterbarhet (Innen serie)

Ikke relevant

#### Reproduserbarhet (Dag til dag)

Vi benytter kontrollen Liquichek Urinanalysis Level 1 og level 2 i ca. 20 dager for å få et mål for dag-til-dag variasjonen.

### Krav:

Analysesvarene må samsvare med resultatet som er oppgitt som fasit for kvalitetskontrollene.

### Sammenligning mellom laboratorier, SLP

## Vi deltar i Labquality/NKK sitt kvalitetsprogram med 2 kontroller for pH og spesifikk vekt 2 ganger hvert år.

Vi er med i NOKLUS sitt kvalitetsprogram 1 gang pr år for urinstiks.

Dette vil vi fortsette med for de nye instrumentene.

### Måleusikkerhet

Måles ved mellom-dag analysering av kontroll i to nivå.

**Tillatt totalfeil**

Ukjent

### Referanseområdet

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Analytt | Refranseverdi pr i dag08.13 | Leverandør | Benevning |  |
| Leukocytter | < 5 | Neg | Leuko/µL |  |
| Nitritt | Negativ | Neg | µmol/L |  |
| Protein | < 0,03 | Neg | g/L |  |
| Glukose | < 1,0 | Neg | mmol/L |  |
| Erytrocytter | Negativ | Neg | Ery/µL |  |
| Ketoner | Negativ | Neg | mmol/L | Utgis viss rekvirert |
| Urobilinogen | Normal | Neg | µmol/L | Utgis viss rekvirert |
| Bilirubin | Negativ | Neg | µmol/L | Utgis viss rekvirert |
| pH | 5,0 – 6,0 | 4,8 – 7,4 |  |  |
| Spesifikk vekt | 1,010 – 1,030 | 1,016 – 1,022 |  | Osmolalitet benyttes |

Det er noe usikkert hvor vi har hentet vårt nåværende referanseverdier fra.

Av den grunn foreslår vi det benyttes samme referanseverdier som leverandør oppgir 3.

**Online overføring**

For å sikre at online overføringer blir riktig skal vi analysere prøver med forskjellig utslag fra hvert instrument. Resultatene av analysene tas ut på egen utskrift fra Cobas u411. Resultatet overføres til NSL via ANP. Når resultatene er overført til NSL, tar vi ut resultatrapportene. Disse kontrollleses mot utskriftene fra cobas u411. Når vi har sjekket dette, kan overføringene godkjennes.

**Planen er sendt på høring til legespesialist, avdelingsleder og driftsleder**

**28.08.2013 Sign: Eva Tingstad**

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| DOKUMENTASJON   **Metodens nøyaktighet og resultatene av forsøkene:**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  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Instrument2 Driftstemperatur: 15 – 32 **ºC**  Fuktighet: 30% - 80 % uten kondens  Leverandør:  Roche Diagnostics AS, pb 6610 Etterstad, 0607 Oslo.  Tlf: 23373300 Produkter2, 4 Combur10-Test M teststrimmel  Teststrimmel med 10 felt  Oppbevares i romtempeatur  i originalbeholderen, tett lukket.  Holdbar til utløpsdato  Leverandør:  Roche Diagnostics AS, pb 6610 Etterstad, 0607 Oslo.  Tlf: 23373300 Standard/Kalibrator3 Control Test M kalibreringsstrimmel  Kalibreringsverdiene er fastsatt med referanse til en hvit standard og er gjemt i de respektive analyseinstrumentenes software.  Oppbevares i romtemperatur, liggende.  Strimlene må ikke fryses eller utsettes for direkte sollys.  Oppbevares i originalbeholderne, tett lukket.  Holdbar til utløpsdato.  Leverandør:  Roche Diagnostics AS, pb 6610 Etterstad, 0607 Oslo.  Tlf: 23373300 Kontroller4Liquichek Urinanalysis Control Level 1 og Level 2Kontrollene oppbevares ved 2 - 8 ºC Åpnet er de stabile i romtemperatur i 30 dager.  Kontrollene skal ikke fryses. Holdbar til utløpsdato ved riktig lagring. Leverandør:  Biorad Laboratories AB, Vintergatan 1, S-172 22, Sundbyberg.  Tlf: 23384130  **Preanalytiske forhold1** UrinFrisklatt, usentrifugert urin benyttes.Skal ikke stå mer enn 2 timer før analysering. Viss lengre, bland godt før bruk.Skal ikke tilsettes konserveringsmiddel.Benytt rene rør til urin.Refeanseløsning Kalibreringsverdiene er fastsatt med referanse til en hvit standard og er gjemt i de respektive analyseinstrumentenes software. Metodenes ytelse oppgitt av leverandør2 **Måleområde**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Analyse** | **Måleområde og tilsvarende SI-enheter.** | | | | | | | | | PH | 5 | 6 | 6,5 | 7 | 8 | 9 | | | | Leukocytter | Neg | 1+  25/µL | | 2+   100/µL | | 3+ 500/µL | | | | Nitritt | Neg | | | Pos | | | | | | Albumin | Neg | 1+  0,25g/L | | 2+   0,75g/L | | 3+  1,5g/L | 4+  5,0g/L | | | Glukose | Neg | 1+  3mmol/L | | 2+   6mmol/L | | 3+  17mmol/L | 4+  56mmol/L | | | Ketoner | Neg | 1+  0,5mmol/L | | 2+   1,5mmol/L | | 3+  5mmol/L | 4+  15mmol/L | | | Urobilinogen | Neg | 1+  17µmol/L | | 2+   68µmol/L | | 3+  135µmol/L | 4+  203µmol/L | | | Bilirubin | Neg | 1+  17μmol/L | | 2+   50μmol/L | | 3+  100μmol/L | | | | Erytrocytter / Blod | Neg | 1+  10/µL | | 2+   25/µL | | 3+  50/µL | 4+  150/µL | 5+  250/µL |     **SENSITIVITET**  Analytisk sensitivitet:   |  |  | | --- | --- | | Sp.vekt | not applicable | | pH | not aplicable | | LEU | 20 -25 Leu/μl | | NIT | 0,05 – 0,07 mg/dL | | PRO | 12 – 18 mg/dL | | GLU | 30 – 40 mg/dL | | KET | 3 – 6 mg/dL | | UBG | 1 – 1,6 mg/dL | | BIL | 0,4 – 0,6 mg/dL | | ERY/Hb | 5 -10 Ery/ μl  (0,012 – 0,030 mg/dL) |   **Robusthet**  Akseptert bøying av teststrimler  - våt + 5 mm  - tørr + 2 mm  **Presisjon**  Innen-dag  Control Test M < 0,5 % Remisjon  Dag til dag  Control Test M < 1,5 % Remisjon  **Våre målinger:**  **Riktighet**  **Pasientprøver:**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Labnr. | Analytt | Miditron | Cobas MB | Cobas plab | Konklusjon | |  | Sp. vekt |  |  |  |  | | 47065666 | 02.09.13 | 1,010 | 1,015 | 1,010 | OK +1 | | 47067632 | 08.09.13 | 1,010 | 1,010 | 1,010 | OK | | 47067624 | 08.09.13 | 1,010 | 1,015 | 1,015 | OK +1 | | 47067259 | 06.09.13 | 1,010 | 1,010 | 1,010 | OK | | 47067221 | 06.09.13 | 1,020 | 1,020 | 1,020 | OK | | 47067235 | 06.09.13 | 1,005 | 1,005 | 1,005 | OK | | 47067213 | 06.09.13 | 1,015 | 1,015 | 1,015 | OK | | 47067238 | 06.08.13 | 1,005 | 1,010 | 1,010 | OK +1 | | 4706813 | 09.09.13 | 1,025 | 1,025 | 1,025 | OK | | 1,005 | 09.09.13 | 1,005 | 1,005 | 1,005 | OK | |  | pH |  |  |  |  | | 47065666 | 02.09.13 | 6,5 | 6 | 6,5 | OK -1 | | 47067632 | 08.09.13 | 7 | 7 | 7 | OK | | 47067624 | 08.09.13 | 6 | 6 | 6 | OK | | 47067259 | 06.09.13 | 6,5 | 6,5 | 6,5 | OK | | 47067221 | 06.09.13 | 5 | 5 | 5 | OK | | 47067235 | 06.09.13 | 7 | 7 | 7 | OK | | 47067213 | 06.09.13 | 6 | 6 | 6 | OK | | 47067213 | 06.09.13 | 8 | 8 | 8 | OK | | 4706813 | 09.09.13 | 5 | 5 | 5 | OK | | 4707689 | 09.09.13 | 7 | 7 | 7 | OK | |  | Leukoccytter |  |  |  |  | | 47065666 | 02.09.13 | 500 | 500 | 500 | OK | | 47067632 | 08.09.13 | Neg | neg | neg | OK | | 47067624 | 08.09.13 | 100 | 500 | 500 | OK | | 47067259 | 06.09.13 | neg | neg | neg | OK | | 47067221 | 06.09.13 | 100 | 100 | 100 | OK | | 47067235 | 06.09.13 | 500 | 500 | 500 | OK | | 47067213 | 06.09.13 | 25 | 25 | 25 | OK | | 47067238 | 06.08.13 | 500 | 500 | 500 | OK | | 4706813 | 09.09.13 | 100 | 100 | 100 | OK | | 4707689 | 09.09.13 | 100 | 100 | 100 | OK | |  | Nitritt |  |  |  |  | | 47065666 | 02.09.13 | pos | pos | pos | OK | | 47067632 | 08.09.13 | neg | neg | neg | OK | | 47067624 | 08.09.13 | neg | neg | neg | OK | | 47067259 | 06.09.13 | pos | pos | pos | OK | | 47067221 | 06.09.13 | neg | pos | pos | Nei +1 | | 47067235 | 06.09.13 | pos | pos | pos | OK | | 47067213 | 06.09.13 | neg | neg | neg | OK | | 47067238 | 06.08.13 | pos | pos | pos | OK | | 4706813 | 09.09.13 | neg | neg | neg | OK | | 4707689 | 09.09.13 | neg | neg | neg | OK | |  | Protein |  |  |  |  | | 47065666 | 02.09.13 | neg | 0,25 | 0,25 | Nei +1 | | 47067632 | 08.09.13 | neg | neg | neg | OK | | 47067624 | 08.09.13 | neg | neg | neg | OK | | 47067259 | 06.09.13 | neg | neg | neg | OK | | 47067221 | 06.09.13 | 0,75 | 0,75 | 0,75 | OK | | 47067235 | 06.09.13 | 0,25 | 0,25 | 0,25 | OK | | 47067213 | 06.09.13 | 0,75 | 0,75 | 0,75 | OK | | 47067238 | 06.08.13 | neg | neg | neg | OK | | 4706813 | 09.09.13 | 0,25 | 0,25 | 0,25 | OK | | 4707689 | 09.09.13 | 0,75 | 0,75 | 0,75 | OK | |  | Glukose |  |  |  |  | | 47065666 | 02.09.13 | 6 | 6 | 6 | OK | | 47067632 | 08.09.13 | norm | norm | norm | OK | | 47067624 | 08.09.13 | norm | norm | norm | OK | | 47067259 | 06.09.13 | norm | norm | norm | OK | | 47067221 | 06.09.13 | 6 | 6 | 6 | OK | | 47067235 | 06.09.13 | norm | norm | norm | OK | | 47067213 | 06.09.13 | norm | norm | norm | OK | | 47067238 | 06.08.13 | norm | norm | norm | OK | | 4706813 | 09.09.13 | norm | norm | norm | OK | | 4707689 | 09.09.13 | norm | norm | norm | OK | |  | Ketoner |  |  |  |  | | 47065666 | 02.09.13 | neg | neg | neg | OK | | 47067632 | 08.09.13 | neg | neg | neg | OK | | 47067624 | 08.09.13 | neg | neg | neg | OK | | 47067259 | 06.09.13 | neg | neg | neg | OK | | 47067221 | 06.09.13 | 0,5 | 1,5 | 1,5 | OK +1 | | 47067235 | 06.09.13 | 5 | 1,5 | 1,5 | OK -1 | | 47067213 | 06.09.13 | 0,5 | 0,5 | 0,5 | OK | | 47067238 | 06.08.13 | neg | neg | neg | OK | | 4706813 | 09.09.13 | neg | neg | neg | OK | | 4707689 | 09.09.13 | neg | neg | neg | OK | |  | Urobilinogen |  |  |  |  | | 47065666 | 02.09.13 | norm | norm | norm | OK | | 47067632 | 08.09.13 | norm | norm | norm | OK | | 47067624 | 08.09.13 | norm | norm | norm | OK | | 47067259 | 06.09.13 | norm | norm | norm | OK | | 47067221 | 06.09.13 | 203 | 203 | 203 | OK | | 47067235 | 06.09.13 | norm | norm | norm | OK | | 47067213 | 06.09.13 | 68 | 135 | 68 | OK +1 | | 47067238 | 06.08.13 | norm | norm | norm | OK | | 4706813 | 09.09.13 | norm | norm | norm | OK | | 4707689 | 09.09.13 | norm | norm | norm | OK | |  | Bilirubin |  |  |  |  | | 47065666 | 02.09.13 | neg | neg | neg | OK | | 47067632 | 08.09.13 | neg | neg | neg | OK | | 47067624 | 08.09.13 | neg | neg | neg | OK | | 47067259 | 06.09.13 | neg | neg | neg | OK | | 47067221 | 06.09.13 | 50 | 50 | 50 | OK | | 47067235 | 06.09.13 | neg | neg | neg | OK | | 47067213 | 06.09.13 | 17 | 17 | 17 | OK | | 47067238 | 06.08.13 | neg | neg | neg | OK | | 4706813 | 09.09.13 | neg | neg | neg | OK | | 4707689 | 09.09.13 | neg | neg | neg | OK | |  | Erytrocytter |  |  |  | OK | | 47065666 | 02.09.13 | 25 | 25 | 25 | OK | | 47067632 | 08.09.13 | neg | neg | 10 | OK | | 47067624 | 08.09.13 | neg | neg | neg | OK | | 47067259 | 06.09.13 | neg | neg | neg | OK | | 47067221 | 06.09.13 | 10 | 10 | 10 | OK | | 47067235 | 06.09.13 | 250 | 250 | 250 | OK | | 47067213 | 06.09.13 | neg | neg | neg | OK | | 47067238 | 06.08.13 | 25 | 25 | 25 | OK | | 4706813 | 09.09.13 | 25 | 25 | 25 | OK | | 4707689 | 09.09.13 | 25 | 25 | 25 | OK |   **Analytisk kvalitet**  ***Repeterbarhet (Innen serie)***  Ikke relevant  ***Reproduserbarhet ( Dag til dag)***  ***Liquichek Urinanalysis Level 1 Lot.nr. 61441 Tidsrom; 10.06 -10.07.2013***   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Antall  MB/plab | Analytt | Kontroll  grenser | Cobas MB | Cobas plab | Konklusjon | | 32/26 | Sp. vekt | 1,010-1,020 | 1,010-1,020 | 1,010-1,020 | OK | | 32/26 | pH | 5,0-6,5 | 5,0-6,5\* | 5,0-6,5 | OK | | 32/26 | Leukocytter | Neg | Neg | Neg | OK | | 32/26 | Nitritt | Neg | Neg  4 Pos | Neg  7 Pos | Se diskusjon | | 32/26 | Protein | Neg | Neg | Neg | OK | | 32/26 | Glukose | Norm | Norm | Norm | OK | | 32/26 | Ketoner | Neg | Neg | Neg | OK | | 32/26 | Urobilinogen | Norm | Norm | Norm | OK | | 32/26 | Bilirubin | Neg | Neg | Neg | OK | | 32/26 | Erytrocytter | Neg | Neg | Neg | OK |   \* En måling første dag på pH=8  ***Liquichek Urinanalysis Level 2 Lot.nr. 61442 Tidsrom; 10.06 -10.07.2013***   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Antall  MB/plab | Analytt | Kontroll  grenser | Cobas MB | Cobas plab | Konklusjon | | 30/25 | Sp. vekt | 1,000-1,015 | 1,005-1,015 | 1,010-1,020\* | OK | | 30/25 | pH | 6,5-8,0 | 6,5-7,0 | 6,5-7,0 | OK | | 30/25 | Leukocytter | 25-500 | 100-500 | 100-500 | OK | | 30/25 | Nitritt | Pos | Pos | Pos | OK | | 30/25 | Protein | 0,75-5,0 | 5 | 1,5-5 | OK | | 30/25 | Glukose | 6-56 | 56 | 56 | OK | | 30/25 | Ketoner | 1,5-15 | 15 | 15 | OK | | 30/25 | Urobilinogen | 68-203 | 135-203 | 135-203 | OK | | 30/25 | Bilirubin | 17-100 | 100 | 100 | OK | | 30/25 | Erytrocytter | 50-250 | 250 | 250 | OK |   ***\**** En måling i starten; spesifikk vekt 1,020 |   Kontroller analysert etter justering av refleksjonsverdien på nitritt fra 69,5 % til 71,0%.  ***Liquichek Urinanalysis Level 1 Lot.nr. 61441 Tidsrom; 04.09 -09.09.2013***   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Antall  MB/plab | Analytt | Kontroll  grenser | Cobas MB | Cobas plab | Konklusjon | | 6/7 | Sp. vekt | 1,010-1,020 | 1,015-1,020 | 1,015 | OK | |  | pH | 5,0-6,5 | 6 | 6 | OK | |  | Leukocytter | Neg | Neg | Neg | OK | |  | Nitritt | Neg | Neg | Neg | OK | |  | Protein | Neg | Neg | Neg | OK | |  | Glukose | Norm | Norm | Norm | OK | |  | Ketoner | Neg | Neg | Neg | OK | |  | Urobilinogen | Norm | Norm | Norm | OK | |  | Bilirubin | Neg | Neg | Neg | OK | |  | Erytrocytter | Neg | Neg | Neg | OK |   ***Liquichek Urinanalysis Level 2 Lot.nr. 61442 Tidsrom; 04.09 -09.09.2013***   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Antall  MB/plab | Analytt | Kontroll  grenser | Cobas MB | Cobas plab | Konklusjon | | 4/4 | Sp. vekt | 1,000-1,015 | 1,005-1,015 | 1,010-1,015 | OK | |  | pH | 6,5-8,0 | 6,5-7,0 | 6,5-7,0 | OK | |  | Leukocytter | 25-500 | 100-500 | 500 | OK | |  | Nitritt | Pos | Pos | Pos | OK | |  | Protein | 0,75-5,0 | 1,5 | 1,5-5 | OK | |  | Glukose | 6-56 | 56 | 56 | OK | |  | Ketoner | 1,5-15 | 15 | 15 | OK | |  | Urobilinogen | 68-203 | 135-203 | 135-203 | OK | |  | Bilirubin | 17-100 | 100 | 100 | OK | |  | Erytrocytter | 50-250 | 250 | 250 | OK |  DISKUSJON **Pasientprøver:**  Analyttene protein og nitritt har 10% avvik, 1 av 10 med +1 avvik ved avlesning på instrumentene. Disse avvik vil gi en annen konklusjon, men de er innen de kriterier vi har satt. De to nye instrumentene viser samme svar.    **Analytisk kvalitet:**  Dag til dag analysering av kontrollene viste at negativ kontroll enkelte ganger ga positivt utslag på nitritt. Dette er en viktig analytt, så leverandør er kontaktet. De anbefalte oss å justere på refleksjonsverdien for nitritt. Den ble forandret fra 69,5% til 71,0% den 04.09.2013.  Kontrollene er analysert etter justeringen, og de viser fine resultat. Dette vil bli fulgt opp ved daglige kontroller av instumentene når de kommer i rutinen.  De andre anlyttene viser god overensstemmelse med oppgitte verdier.  **Online overføring:**  Testet og funnet at verdiene går over 11.09.2013 av Fred Ingvaldsen.  Resten av testinga utføres ved oppstart. Referanseområdet  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Analytt | Refranseverdi pr i dag08.13 | Leverandør | Benevning |  | | Leukocytter | < 5 | Neg | Leuko/µL |  | | Nitritt | Negativ | Neg | µmol/L |  | | Protein | < 0,03 | Neg | g/L |  | | Glukose | < 1,0 | Neg | mmol/L |  | | Erytrocytter | Negativ | Neg | Ery/µL |  | | Ketoner | Negativ | Neg | mmol/L | Utgis viss rekvirert | | Urobilinogen | Normal | Neg | µmol/L | Utgis viss rekvirert | | Bilirubin | Negativ | Neg | µmol/L | Utgis viss rekvirert | | pH | 5,0 – 6,0 | 4,8 – 7,4 |  |  | | Spesifikk vekt | 1,010 – 1,030 | 1,016 – 1,022 |  | Osmolalitet benyttes |   Referanseområdet er hentet fra leverandør. KONKLUSJON .  Vi godkjenner urinstiks analysert på cobas u 411 og referanseområdet til bruk i vårt sykehus.  13.09.2013 Eva Tingstad  Instrumentet tas i bruk 13.09.2013 etter at følgende er utført;   * Endringer av referanseverdiene (NSL, ANP, Labhåndbok) Dette blir utført etter at instumentene er tatt i bruk. * Informasjon til rekvirentene via labnytt * Bestille nytt ikon på IP-programmet. HEMIT kontaktes. * Ny prosedyre for urinstiks på cobas u411 * Informasjon internt   Valideringen er utført i tidsrommet f.o.m.: 13.06– 11.09.2013 av Sign: ET Oppbevaring av valideringsrapport Valideringsrapporten er EQSDocument: 18280 v1.1.  GODKJENNING |
| **Valideringsrapporten sendes til godkjenning via EQS til:**  **Driftsleder**  **Avdelingsleder**  **Legespesialist** |

**TILLEGG TIL VALIDERINGSRAPPORT COBAS U411**

**EQS 18280 versjon 1.1.**

**Nytt urinstiks/urinstrimmel- instrument, Cobas u411 fra Roche Diagnostics Norge AS, på prøvetakingslaboratoriet (MB-L).**

Det ble anskaffet et nytt instrument som erstatning for ødelagt Cobas u411 (Modell: 04906969001, kode: 12523-00003), pga: defekt skjerm. Skjermen ble antakelig ødelagt ved statisk utladning da bruker følte at det smalt da hun tok på den. Det viste seg at å få reparert skjerm var forholdsmessig dyrt i forhold til å kjøpe nytt instrument.

Innkjøpsdato nytt instrument: 27.12.2017. Det nye instrumentet er identisk med det som ble ødelagt.

Registreringsnummer i Medusa for nytt instrument: 69856. (Modell: 04906969001, Kode: 12523-00003. Fabrikat: Roche). Registrert og utført mottakskontroll av Medisinsk teknisk avdeling, Tom Børge Buberg 09.01.2018: «Registrert, lagt inn konfig fra instrumentet på prøvetaking. Lagt inn ca timer fra bestillingsprosess og til utlevering.»

Plassert på lab: 09.01.18 (Garanti t.o.m 09.01.2019).

I og med at instrumentene er identiske ble konfigurasjon fra ødelagt instrument lagt inn i det nye og følgende ble sjekket og funnet OK:

* Lotnr på kalibreringsstrimmel
* Lotnr på prøvestrimmel
* Lotnr på Biorad-kontroller (Level 1 og 2)

**Validering:**

Det gjøres en svært enkel validering da det nyinnkjøpte instrumentet er identisk med det som gikk i stykker:

* Instrumentet kalibreres iflg leverandørs spesifikasjoner.
* Kontroller analyseres i 2 nivå. Godkjennes iflg leverandørs oppgitte verdier.
* Samkjøre minimum 10 urinprøver med instrumentet på urinlab (MB). Godkjennes hvis forskjellen ikke er større enn +/- et trinn på «resultatskala». Dette pga at vi ikke har noe SLP resultat tilgjengelig, noe vi har for instrumentet på urinlab.
* Kontrollere at svar overføres korrekt fra instrument til NSL via ANP.

**Resultat:**

* 10.01.18. ble instrumentet kalibrert og godkjent iflg leverandørs spesifikasjoner.
* Kontroller i 2 nivå fra Biorad, Liquichek Urinanalysis Bilevel, ble analysert i 5 dager (10.01. tom 18.01.18). Alle kontroller innenfor leverandørs oppgitte verdier. Se vedlagt regneark: 01\_jan 2018 Urinkontroller\_PTLAB\_CobasU411.
* Det ble valgt ut urinprøver som var analysert på urinlab i rutinen (rekvirert u-stiks). Prøver med resultat i ulike nivå for de ulike parameterne ble valgt. Prøvene er analysert 10,11 og 18. januar 2018. Resultat angitt i tabell:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pr.nr | Analytt |  |  |  |  | Analytt |  |  |  |
|  |  | PTLAB | MB | Konklusjon |  |  | PTLAB | MB | Konklusjon |
|  | Sp.vekt |  |  |  |  | pH |  |  |  |
| 47102725 |  | 1,005 | 1,010 | OK -1 |  |  | 7 | 8 | OK -1 |
| 47087218 |  | 1,010 | 1,005 | OK +1 |  |  | 6,5 | 6,5 | OK |
| 47109375 |  | 1,020 | 1,025 | OK -1 |  |  | 5 | 5 | OK |
| 47101742 |  | 1,020 | 1,020 | OK |  |  | 5 | 5 | OK |
| 47003511 |  | 1,010 | 1,010 | OK |  |  | 6,5 | 6,5 | OK |
| 47004340 |  | 1,015 | 1,015 | OK |  |  | 6,5 | 6,5 | OK |
| 47004344 |  | 1,020 | 1,015 | OK +1 |  |  | 5 | 5 | OK |
| 47004276 |  | 1,020 | 1,015 | OK +1 |  |  | 5 | 5 | OK |
| 47004153 |  | 1,015 | 1,015 | OK |  |  | 5 | 6 | OK -1 |
| 47106159 |  | 1,015 | 1,015 | OK |  |  | 5 | 5 | OK |
| 47102024 |  | 1,010 | 1,010 | OK |  |  | 6 | 6 | OK |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | PTLAB | MB | Konklusjon |  |  | PTLAB | MB | Konklusjon |
|  | Leukoc |  |  |  |  | Nitritt |  |  |  |
| 47102725 |  | 500 | 500 | OK |  |  | neg | neg | OK |
| 47087218 |  | 25 | 25 | OK |  |  | neg | neg | OK |
| 47109375 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47101742 |  | 500 | 500 | OK |  |  | neg | neg | OK |
| 47003511 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47004340 |  | 25 | neg | OK +1 |  |  | neg | neg | OK |
| 47004344 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47004276 |  | 100 | 100 | OK |  |  | pos | pos | OK |
| 47004153 |  | 500 | 500 | OK |  |  | neg | neg | OK |
| 47106159 |  | 500 | 500 | OK |  |  | pos | pos | OK |
| 47102024 |  | 500 | 500 | OK |  |  | neg | neg | OK |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | PTLAB | MB | Konklusjon |  |  | PTLAB | MB | Konklusjon |
|  | Protein |  |  |  |  | Glukose |  |  |  |
| 47102725 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47087218 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47109375 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47101742 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47003511 |  | 0,25 | neg | OK +1 |  |  | neg | neg | OK |
| 47004340 |  | 1,5 | 1,5 | OK |  |  | neg | neg | OK |
| 47004344 |  | 0,25 | 0,25 | OK |  |  | neg | neg | OK |
| 47004276 |  | 0,75 | 1,5 | OK -1 |  |  | neg | neg | OK |
| 47004153 |  | 1,5 | 1,5 | OK |  |  | 18 | 56 | OK -1 |
| 47106159 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47102024 |  | neg | neg | OK |  |  | neg | neg | OK |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | PTLAB | MB | Konklusjon |  |  | PTLAB | MB | Konklusjon |
|  | Ketoner |  |  |  |  | Urobili |  |  |  |
| 47102725 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47087218 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47109375 |  | neg | neg | OK |  |  | neg | 17 | OK -1 |
| 47101742 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47003511 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47004340 |  | 0,5 | neg | OK +1 |  |  | neg | neg | OK |
| 47004344 |  | 1,5 | 1,5 | OK |  |  | 17 | 17 | OK |
| 47004276 |  | neg | neg | OK |  |  | 68 | 135 | OK -1 |
| 47004153 |  | neg | 0,5 | OK -1 |  |  | neg | neg | OK |
| 47106159 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47102024 |  | neg | neg | OK |  |  | neg | neg | OK |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pr.nr | Analytt |  |  |  |  | Analytt |  |  |  |
|  |  | PTLAB | MB | Konklusjon |  |  | PTLAB | MB | Konklusjon |
|  | Bilirubin |  |  |  |  | Erytroc |  |  |  |
| 47102725 |  | neg | neg | OK |  |  | 10 | 10 | OK |
| 47087218 |  | neg | neg | OK |  |  | neg | neg | OK |
| 47109375 |  | neg | 17 | OK -1 |  |  | 25 | 25 | OK |
| 47101742 |  | 17 | 17 | OK |  |  | 25 | 25 | OK |
| 47003511 |  | neg | neg | OK |  |  | 10 | 10 | OK |
| 47004340 |  | neg | neg | OK |  |  | 10 | 10 | OK |
| 47004344 |  | 17 | 17 | OK |  |  | 25 | 25 | OK |
| 47004276 |  | 17 | 17 | OK |  |  | 150 | 150 | OK |
| 47004153 |  | neg | neg | OK |  |  | 250 | 250 | OK |
| 47106159 |  | neg | neg | OK |  |  | 10 | 10 | OK |
| 47102024 |  | neg | neg | OK |  |  | neg | neg | OK |

Alle resultat er innenfor de satte krav: Ingen prøvesvar har større forskjell enn +/- et trinn på «resultatskala», angitt som +1 og -1 i tabellen.

Følges opp med SLP ved neste utsendelse fra NOKLUS.

* Svaroverføring via ANP fra Cobas u411 til NSL ble skjekket for 4 pasientsvar. Disse ble korrekt overført.

Instrumentet er tatt i rutinemessig bruk 19.01.2018, før valideringsrapport er ferdigstilt. Resultat mm var gjennomgått og sett at instrumentet var ok og klar til bruk. Det er skrevet en fraviksmelding på dette: Meldings-ID: 19272 -«Fraviksmelding for Cobas u411 P.lab».

Siri Amundsen 01.03.18

Fagbioingeniør