skyla

Thyroid/T4 Panel

For Veterinary In Vitro Diagnostic Use Only

PN：900-160
Rev：G

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1. Intended Use

The skyla Thyroid/T4 Panel used with skyla Analyzer, is intended to be used for the quantitative determination of Thyroxine (T4) and Total cholesterol (CHOL) in animal whole blood, plasma, or serum.

2. Principles

The skyla Thyroid/T4 Panel contains 2 dried reagents located in the respective detection wells of the reagent disc. The user only needs to inject the blood specimens into the sample port of the disc, and then places the disc into the analyzer. The test will be done automatically within 15 minutes. For the detail description of disc, please refer to “skyla Analyzer Operator’s Manual”.

Clinical Significance:

Thyroxine (T4): The thyroid gland can synthesize and secret thyroxine. Determination of thyroxine is one of the indicators for the function of the thyroid gland.

Total Cholesterol (CHOL): CHOL test can be used to assess the metabolic state of lipids.

Method:

T4

T4 is determined through the competitive enzyme immunoassay method. When endogenous T4 competes for specific T4 antibody binding sites with T4-G6PDH, the production rate of NADH in this reaction will be changed. INT is participated in the reaction which forms a product from orange to red. The concentration of endogenous T4 can be calculated by absorbance at a wavelength of 510 nm.

CHOL

CHOL is determined enzymatically by an endpoint reaction. It is hydrolyzed by Cholesterol Esterase (COE) into free Cholesterol and Fatty Acids. Cholesterol and NAD reacts with Cholesterol Dehydrogenase (CDH) to produce Cholest-4-En-3-One and NADH. The absorbance at the wavelength of 340 nm can be measured in the presence of NADH. The absorbance is proportional to

the TC concentration.

Reaction pathway:

T4

$$T4 + T4\text{-}G6PDH + NAD^+ \xrightarrow{Ab} Ab{:}T4 + Ab{:}T4\text{-}G6PDH + NADH + H^+$$

$$NADH + H^+ + INT \xrightarrow{Diaphorase} NAD^+ + Formazan$$

CHOL

$$Cholesterol\ Esters + H_2O \xrightarrow{COE} Cholesterol + RCOOH$$

$$Cholesterol + NAD \xrightarrow{CDH} Cholest\text{-}4\text{-}En\text{-}3\text{-}One + NADH + H^+$$

3. Reagents

Included:

Each panel contains dried reagent beads, dried internal QC beads and the diluent.

Reagent Composition:

Composition	Quantity/Panel
Cholesterol Dehydrogenase	0.25 U
Cholesterol Esterase	2.4 U
Diaphorase	0.3 U
Glucose 6 phosphate	0.20 mg
INT	0.01 mg
NAD	0.36 mg
T4-G6PDH	0.1 U
T4 monoclonal antibody	0.60 ug

Reagent Storage:

- The reagent disc should be stored at 2～8°C.
- The expiry date of the reagent is printed on the outside of the sealed pouch of reagent disc. Do not use if the reagent disc has expired.

4. Specimen Collection and Preparation

Specimen Collection:

- Specimens suitable for skyla Thyroid/T4 Panel include lithium heparinized whole blood, lithium heparinized plasma, serum and quality control materials. The sample requirement

is 200 µL. (± 10 µL tolerance are allowable)

- If applicable, local regulatory or standard operating procedures of your organization should be followed for the collection, preservation and handling of specimens.

Note: Do not use specimens containing other coagulants. That would cause an incorrect test results.

Specimen Preparation:

- Before applying a sample to the reagent disc, gently rotate the sample tube up and down several times, to confirm the sample is homogeneous (evenly mixed). If the sample is whole blood, do not shake the sample container vigorously to avoid occurrence of hemolysis.

Note:

1. Perform testing within 10 minutes after applying the sample to the reagent disc.
2. The use of whole blood specimens with hematocrits (Hct) higher than 60% may affect the test results.

Note: For further information in specimen collection and preparation, please refer to "skyla Analyzer Operator's Manual"

5. Test Procedures

Material Preparation:

1 piece of the reagent disc of skyla Thyroid/T4 Panel

Required materials not included in the panel:

skyla Analyzer

Sample collection container

Micropipette / Tips

Test Conditions:

Test should be carried out in an environment with temperatures of 10°C~32°C. Each test will take about 15 minutes. During the test, chamber in the analyzer keeps the temperature at 37°C for stable assay.

Test Steps:

1. Open the aluminum pouch and remove the reagent disc.
2. Remove the diluent container sealing.
3. Using a micropipette to inject 200 µL of the sample into the reagent disc through the sample

port.

4. Press the “start” button on the screen to initiate testing.
5. Place the reagent disc to the analyzer drawer, and press the “ok” button on the screen to analysis.

For details on the operating steps and instrument setting, please refer to “skyla Analyzer Operator’s Manual”.

Note:

1. To operate the reagent disc or instrument, please wear lab gloves and other protective gear to avoid contamination by specimen.
2. The used reagent disc and tips should be discarded as biomedical waste, and treat according to the local legal requirements.
3. Testing should be performed within 20 minutes after the pouch is opened.
4. Do not place the reagent disc at the environment more than 25°C and longer than 48 hours prior to use.
5. If the reagent disc or its package is damaged or is over the expiry date, do not use it.

6. Calibration

The barcode on every manufactured reagent disc contains all information required for calibration of the test items. The analyzer will automatically read the barcode information during testing.

7. Quality Control

- Please refer to the instruction manual for the preparation and use of quality control materials. For discrepancy results, the confirmatory test was suggested to carry out with the automated laboratory analyzer, or to contact with our technical support.
- External quality control materials can be used for the accuracy monitor of skyla system. The recommended frequency of QC testing is as follows, otherwise please follow local legal requirements or the standard operating procedures of your organization
  - At least every 30 days.
  - Before a new batch of reagents is used for testing.
  - When the analyzer was moved or the operating environment significantly changed.

8. Reference interval

The table below shows the reference interval for each test item. It is recommended that every laboratory or test site should establish its own reference interval from its patient population.

Test Item		Reference Interval		Reference Interval (SI Unit)	
T4	Canine	1.0 – 4.0	g/dL	12.9 – 51.5	nmol/L
	Feline	0.8 – 4.7	g/dL	10.3 – 60.5	nmol/L
CHOL	Canine	110 – 320	mg/dL	2.85 – 8.29	mmol/L
	Feline	54 – 220	mg/dL	1.40 – 5.70	mmol/L

9. Limitation

Physiological interferences in blood include hemolysis, icterus, and lipemia. For every test item, 2 Levels serum pool supplemented with known concentrations of the endogenous substances were used for the testing. Significant interference is defined as a >20% shift in the test result. (Note: Highest tested concentration for Hemoglobin: 600 mg/dL; Bilirubin (unconjugated): 25.0 mg/dL, Bilirubin (conjugated): 57.5 mg/dL; Intralipid: 0.1%)

Test Item	Substance concentration with interferences of less than 20%			
	Hemoglobin	Bilirubin (unconjugated)	Bilirubin (conjugated)	Intralipid
T4	100 mg/dL	25.0 mg/dL	57.5 mg/dL	0.1%
CHOL	300 mg/dL	30.0 mg/dL	30.0 mg/dL	0.2%

10. Performance Characteristics

Dynamic range:

The dynamic range for each test item showed as below.

Test Item	Dynamic Range		Dynamic Range (SI Unit)	
T4	0.5 – 7.0	µg/dL	6.4 – 90.1	nmol/L
CHOL	50-540	mg/dL	1.30 – 13.99	mmol/L

Method Comparison:

The IDEXX SNAPshot Dx was used as comparative method in the study. The tests are performed by using the same clinical serum sample for two methods.

Marker		R^2	Slope	Intercept	Sample No.	Sample Range	
T4	Canine	0.9547	1.0059	-0.0476	34	0.6-4.8	g/dL
	Feline	0.9468	0.9503	0.2243	24	1.1-7.0	g/dL
CHOL	Canine	0.9944	0.9115	2.840	12	98-310	mg/dL
	Feline	0.9899	1.0557	-10.199	15	84-220	mg/dL

Symbol Index			
	Catalogue number		Consult instruction for use
	Batch code		Use by
	Manufacturer		CE mark
	Temperature limitation		Caution
	Do not reuse		Sufficient for

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