PANTEX

Division of
Bio-Analysis, Inc

PANTEX SALIVARY DIRECT TESTOSTERONE EIA KIT

For In-Vitro Diagnostic Use (IVD)

Catalog Number: 635

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I. Intended Use

The Pantex Salivary Direct Testosterone EIA Kit is an Enzyme Immunoassay (EIA) for the quantitative measurement of testosterone in human saliva collected with the Pantex Sample Collection Device. The measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males and in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and adrenogenital syndromes.

For further information about this kit, its application or the procedures in this insert, please contact the Technical Service Team at Pantex.

II. Assay Background

Assessment of androgen function in both males and females has previously depended upon indirect parameters such as measurement of urinary excretion of 17-ketosteroids. This procedure measures the excretory products of several weakly androgenic substances secreted by adrenal glands and gonads. However, testosterone, which appears to be the major effective androgen in the female as well as in the male, is not excreted as a 17-ketosteroid.

The accurate diagnosis of male hypogonadism is now made possible by measurement of serum testosterone. If testosterone measurements are low, a simultaneous determination of serum LH will differentiate primary testicular disease from hypogonadism secondary to pituitary disease. Because of the feedback relationship between the testis and pituitary, LH levels should be high in the presence of low testosterone due to primary gonadal disease.

Studies of testosterone values in hirsute women have shown higher mean values of testosterone as compared to normal women, although overlap occurs with the normal range (1). Patients with elevated levels treated pharmacologically with such agents as dexamethasone have frequently shown reduction in testosterone levels (2,3). Very high values seen in women with hirsutism and menstrual irregularities suggest the possibility of adrenal or ovarian tumors. Estrogen treatment or pregnancy will also cause increase in total testosterone levels due to increases in sex hormone binding globulin (SHBG). In these situations, the physiologically active or free component of testosterone remains normal.

Only1-2% of the testosterone circulating in plasma is free, the rest is bound to serum proteins and especially to SHBG and albumin. The free fraction reflects the metabolically available portion of testosterone and it is therefore clinically important (4,5).

In saliva, testosterone occurs in the free form and enters the saliva via intracellular mechanisms (6) and reflects the level of free testosterone in plasma.

Measuring free testosterone in saliva is therefore a simple, convenient and non-invasive method due to easier sample collection eliminating the need for repeated venipunctures.

III. Assay Principle

The Pantex Salivary Direct Testosterone EIA kit, Cat # 635 is based on the competition principal and microplate separation. Testosterone calibrators of known concentration, unknown amounts of testosterone in saliva samples and a fixed amount of testosterone (analog) conjugated to horse radish peroxidase (Testosterone-HRP) compete for binding sites with a rabbit monoclonal antiserum bound to GARGG (goat anti-rabbit gamma globulin) coated wells of a microplate. After incubation, unbound components are washed away, enzyme substrate solution is added and a blue color formed. This reaction is stopped with an acid solution to produce a yellow color. The optical density is then read at 450 nm. The amount of Testosterone-HRP detected is inversely proportional to the amount of testosterone in a sample.

IV. Reagents Supplied and Reagent preparation

Store all reagents at 2 to 8°C. Use only reagents supplied with this kit. Do not interchange reagents with different lot numbers. Expiration dates and lot numbers are printed on the labels.

1. GARGG Plate: One 96 well microplate (12x8 breakable strip wells) coated with goat anti-rabbit gamma globulin placed in a resealable foil bag with desiccant. One (1) 96 well kit is sufficient for 39 duplicate patient measurements.
2. **Concentrated Stock Testosterone (synthetic) solution** in BSA buffer at a concentration of 62.5 ng/ml (62,500 pg/ml): 1 bottle, 250 ul.
   Salivary Testosterone working calibrators preparation: Dilute the 62,500 pg/ml stock solution 1:100 (1 part 62,500 pg/ml + 99 parts assay buffer) with assay buffer to obtain the highest working calibrator (625 pg/ml) then, dilute serially 1:2.5 (starting with the 625 pg/ml calibrator) to obtain the following concentrations of **working calibrators**: 250 pg/ml, 100 pg/ml, 40 pg/ml, 16 pg/ml and 6.4 pg/ml. "0" calibrator is assay buffer.
   Note: A 1:2.5 dilution is defined as 1 part calibrator in question plus 1.5 parts assay buffer.
3. Assay buffer: 1 bottle, 20 ml.
4. **Stock Testosterone (synthetic) Control Concentrate (20,000 pg/ml)**: 1 bottle, 0.250 ml. Concentration is on the label and is traceable to U.S. Pharmacopeia (USP). Use for the preparation of **High Control** only.

High Control preparation (Example)

Stock Testosterone control concentrate 20,000 pg/ml	Assay Buffer (ml)	Dilution	Target pg/ml	Number of EIA tests per 2.5 ml volume	Volume (ul) to be used per assay well
0.025 ml (25 ul)	**2.475 ml**	**1:100**	**200 pg/ml**	**100**	**25 ul**

Low Control Preparation (Example)

High Testosterone control 200 pg/ml	Assay Buffer (ml)	Dilution	Target Pg/ml	Number of EIA tests per 2.5 ml volume	Volume (ul) to be used per assay well
0.25 ml	**2.25 ml**	**1:10**	**20 pg/ml**	**100**	**25 ul**

Immediately after use, store the unused portions of the **working calibrators** and the **High** and **Low Controls** 8°C. Discard if not used within 31 days of mixing.

5. **Salivary Testosterone EIA rabbit monoclonal Antibody**: 1 bottle, 6 ml. The solution is blue.
6. **Salivary Testosterone-Horseradish Peroxidase (HRP) concentrate.:** 1 amber bottle, 0.350 ml. Testosterone derivative is conjugated to horseradish peroxidase. The solution is yellow and light sensitive.
7. **Testosterone-Horseradish Peroxidase (HRP) conjugate buffer, pH 7.4**: 1 bottle, 6 ml of phosphate buffered saline, pH 7.4. To be used to prepare the **Testosterone-HRP working reagent only**.
   Testosterone-HRP working reagent preparation: Determine the amount of **working Testosterone-HRP** needed and dilute 1:20 with conjugate buffer pH 7.4 (#7). For example, mix 0.25 ml of **Testosterone-HRP concentrate** (#6) plus 4.75 ml with **conjugate buffer, pH 7.4** (#7). This is sufficient for 100 EIA wells.
   Immediately after use, store the unused portion of the **Testosterone-HRP working reagent** at 2-8°C. Discard if not used within 31 days of mixing.
8. Wash solution (10X concentrated) EIA #1: 1 bottle, 50 ml of phosphate buffered saline, pH 7.4. Prior to use dilute 1:10 with deionized water.

9. Color Development Reagent EIA #1: 1 amber plastic bottle, 15 ml of Tetramethylbenzidine (TMB) plus hydrogen peroxide. Light sensitive.
10. Stopping Solution EIA #1: 1 bottle of a 15 ml mixture of diluted sulfuric and hydrochloric acid solution.

*Concentration of testosterone calibrators and controls are actual and traceable to US Pharmacopeia (USP) Cat. No. 1646009, Lot J0G360.

V. Kit/Reagent Storage and Stability

1. When stored at 2° – 8° C, unopened reagents will retain activity until the expiration date. Do not use the reagents beyond this date.
2. Use only reagents supplied with this kit. Do not interchange reagents with different lot numbers.
3. Opened reagents must be stored at 2° – 8° C.
4. Microtiter wells must be stored at 2° – 8° C. Once the foil bag has been opened, care should be taken to reseal tightly.
5. Opened kits retain activity for 31 days if stored as described above.
6. Expiration dates and lot numbers are printed on the labels.

VI. Materials Needed But Not Provided

1. Device to dispense very accurately 25 ul of saliva.
2. Multichannel pipettors.
3. Microplate or orbital shake
4. Vortex mixer
5. Microplate washer (not required, plates can be washed manually).
6. Microplate reader capable of reading 450 nm with 4 parameter data reduction or comparable software.
7. Plate sealers.

VII. Materials Required But Supplied Separately

1. Pantex sample collection device, Cat. # PCD 602. (Pantex, 1701 Berkeley Street, Santa Monica, CA 90404)

VIII. Interferences

Using CLSI-A2 Interference Testing in Clinical Chemistry as a guide, an in-vivo simulated experiment was performed after collecting saliva samples from subjects before (control) and after contact (exposed) with five (5) commonly consumed products (coffee, food, gum, alcohol and cigarette smoke). The control and exposed samples were tested with the Pantex Salivary Direct Testosterone EIA Kit, Cat #635. The results indicated no significant differences in salivary testosterone values between the controls and exposed samples.
An additional interference study was conducted using three (3) potential interferants whole blood, sodium azide and thimerosal to determine their effects on salivary testosterone samples. The interferants were tested using the following concentrations 0.05%, 0.10%, 0.25% and 0.5%. Based on the results, it was determined that whole blood, thimerosal and sodium azide affect salivary testosterone samples by either increasing or suppressing testosterone values.

Saliva samples containing any of the three interferants in question should be avoided when using the Pantex Salivary Direct Testosterone EIA Kit, Cat # 635.

IX. Sample Collection and Processing

1. This samples collection and processing procedure must be followed:
   a. Pantex sample collection device, Cat. # PCD602, is required for the collection of saliva samples when determining testosterone concentrations with the Pantex Salivary Direct Testosterone EIA Kit, Cat.#635.
   b. Avoid food consumption, drinking coffee or alcohol, smoking or chewing gum 15 minutes prior to sample collection.
   c. Rinse mouth thoroughly with water 15 minutes prior to collection.
   d. In the **required saliva collection device** (Pantex sample collection device, Cat. #PCD602) collect a minimum of 1 mL, (Use the number 1 marked on the collection tube as a reference), of whole saliva by un-stimulated passive drool by allowing saliva to drip off the lower lip into the graduated collection tube or by allowing saliva to accumulate in the floor of the mouth and spitting it into the collection tube. Label the sample tube with the following information:

      i. Date and time of sample collection
      ii. Patient's name
      iii. Patient's gender
      iv. Patient's date of birth

   e. The sample(s) should be sent as soon as possible after collection to the testing site, they should remain stable under average shipping conditions, including over weekends and holidays and during hot temperatures. If the sample(s) will not be sent the day of collection, store at 2-8°C until ready to be shipped.
   f. Upon sample's arrival to the testing site, the sample(s) should be kept in the collection device to maintain its integrity and freeze (≤ -15°C or below) until day of assay. On day of assay, thaw samples to facilitate precipitation of mucins. Centrifuge at 1500g for ten minutes. Bring samples to room temperature and assay.

2. Sample stability

Storage	20-28°C	37°C	2-8°C	≤-15°C (7 freeze/thaw cycles)	≤-15°C (Long term)
Stability	Up to 7 days	Up to 7 days	Up to 7 days	Up to 7 days	Up to 180 days

3. Sample Shipping, Handling and Storage Conditions Stability

Storage	2-8°C and room temperature during transit	20-28°C	37°C	2-8°C	≤-15°C
In transit stability upon return to the testing site	Up to 9 days				
After returning stability		Up to 7 days	Up to 7 days	Up to 7 days	Up to 7 days

X. Assay Procedure Summary Flow Sheet

Calibrator Testosterone Sample I.D. pg/ml	Calibrator, Control, Sample (ul)	HRP Testosterone Working (ul) solution	Anti-Testosterone (ul)		Diluted 10X wash solution. (ul)		Color Developer (ul)		Stopping solution (ul)	
0	25	50	50	Mix. Incubate for 2 hrs. at Room Temperature, shaking.	300	Wash 3X	125	Mix. Incubate 30 min. at room temperature	125	Mix. Read at 450 nm
6.4	25	50	50		300		125		125	
16	25	50	50		300		125		125	
40	25	50	50		300		125		125	
100	25	50	50		300		125		125	
250	25	50	50		300		125		125	
625	25	50	50		300		125		125	
Control #1	25	50	50		300		125		125	
Control #2	25	50	50		300		125		125	
Sample	25	50	50		300		125		125	

XI. Assay Procedure

1. It is recommended that the calibrators, controls and samples should be tested in duplicate and the mean value should be used to report the results.
2. To the GARGG microplate dispense 25 ul of **working Salivary Testosterone EIA calibrators** (0, 6.4, 16, 40, 100, 250 and 625 pg/ml), controls, and saliva samples.
3. Add 50 ul of **Testosterone-HRP working reagent** to all wells.
4. Add 50 ul of **Testosterone EIA rabbit monoclonal antibody**.
5. Cover microplate with plastic sealer. Incubate by shaking on a microplate orbital shaker set a 500-900 rpm for **2 hrs.** at room temperature.

6. After incubation, decant the contents of the wells. Wash 3 times with 300 ul of **diluted wash solution.** After the 3rd wash, invert GARGG microplate on an absorbent paper and tap dry.
7. Dispense 125 ul of Color Development reagent EIA #1 into each well. Shake briefly (manual). Cover microplate with plastic sealer. Incubate for 30 minutes at room temperature.
8. Dispense 125 ul of Stopping Solution EIA #1 into each microtiter well of the GARGG plate. Shake briefly (manual). Color changes from blue to yellow.
9. Read at 450 nm on a microplate reader within 10 minutes.

Note: If samples exceed the upper end of the measuring range of 500 pg/mL, dilute with zero calibrator and make appropriate concentration correction.

XII. Typical Results

Typical Calibration Curve (Actual assay)			
Calibrators (pg/ml)	Mean Absorbance (450 nm)	% B/Bo	Value (pg/ml)
0	2.47	100.0	0.0
6.4	2.23	90.3	6.4
16	1.83	74.1	16
40	1.14	46.2	40
100	0.45	18.2	100
250	0.19	7.7	250
625	0.11	4.5	625
Control # 1	1.61	65.2	22.0
Control # 2	0.23	9.3	204.0
Sample # 1	2.00	81.1	12.0
Sample # 2	0.31	12.6	151.0
Sample #3	0.18	7.3	260.0

XIII. Determination of Testosterone Concentration

1. Determine the concentrations of the controls and unknowns by interpolation using software capable of logistics using a 4-parameter sigmoid minus curve fit.

Analytical measuring range (AMR)	6.4 pg/ml - 500 pg/ml

Conversion: Testosterone (pg/ml) x 3.47 = pmol/L

Samples with testosterone values greater than 500 pg/ml should be diluted 1:10 with zero (0) calibrator and re-run for accuracy. Obtain the final testosterone concentration by multiplying the diluted sample by 10.

XIV. Quality Control

The expected values for the controls are stated on the label of each control which are included in the kit. The results can only be accepted if the expected values are met. Follow federal, state and local guidelines for testing quality control materials.

XV. Expected Testosterone Normal Ranges

Freshly collected (AM) saliva samples from apparently healthy subjects show the following values:

Female Expected Values:

Subjects (Number)	Age (Age)	Median (pg/mL)	95% Reference Limits (pg/mL)	90% CI (pg/mL)
120	20-49	17.20	3.91 – 40.99	3.70 – 50.0
120	50-70	14.75	4.51 – 34.17	4.2 – 35.1

Male Expected Values:

Subjects (Number)	Age (Age)	Median (pg/mL)	95% Reference Limits (pg/mL)	90% CI (pg/mL)
120	20-49	86.6	41.12 – 142.16	33.6 – 157.9
120	50-70	60.15	24.03 – 119.52	22.0 – 131.9

It is recommend that each laboratory establishes its own range of normal values. Since testosterone is diurnally variable, it is also recommended that saliva samples be collected at approximately the same hour each day.

XVI. Performance Characteristics

A. Specificity of Antiserum

The cross reactivity of the antiserum was determined by spiking three (3) saliva pools (low, medium and high) with two (2) concentrations (10,000 pg/ml and 20,0000 pg/mL) of each potential cross reactant. The percent cross reaction was calculated using the following equation as per CLSI (EP7-A2) guidelines.

$$\% \text{ Cross-reactivity} = 100^* \frac{[\text{measured value} - \text{true value}]}{[\text{Concentration of interferant}]}$$

Where,
Measured value = is the spiked measured value
True value = is the un-spiked obtained value
Concentration of interferant = is the amount of the compound spiked

Compound	Low Testosterone sample (% Cross Reactivity)	Medium Testosterone Sample (% Cross Reactivity)	High Testosterone sample (% Cross Reactivity)
Testosterone	100	100	100
11 β-OH Testosterone	0.407	0.486	0.242
11 α-OH Testosterone	0.869	1.033	0.601
5 α-Dihydro-Testosterone	5.540	5.474	5.347
Androstenedione	0.718	0.876	0.604
Methyl Testosterone	1.410	1.597	0.889
Testosterone SO4	0.005	0.010	0.067
DHEA SO4	0.001	0.001	0.006
DHEA	0.001	0.003	0.006
7-Keto DHEA	0.003	0.004	0.008
Progesterone	0.243	0.276	0.179
Cortisol	0.005	0.002	0.005
17 β-Estradiol	0.175	0.173	0.135
17 α-Estradiol	0.007	0.002	0.008
Cortisone	0.014	0.013	0.013
Danazol	0.011	0.018	0.063
Dexamethasone	0.007	0.025	0.051
D-5-Androstene-3 β, 17 β -diol	0.691	0.827	0.497
Estrone	0.015	0.003	0.012
Ethisterone	0.037	0.050	0.084
Norgestrel	0.033	0.020	0.071
Testosterone propionate	0.068	0.065	0.134
5 α-Androstane-3 β, 17 β-diol	2.497	2.745	2.571
11-Keto Testosterone	0.137	0.158	0.079
Prednisone	0.038	0.009	0.018
Prednisolone	0.023	0.007	0.028

B. Detection limits

The Detection Limit Study for determining the limit of the blank (LoB), limit of detection (LoD) and the limit of quantitation (LoQ) for the Pantex Salivary Direct Testosterone EIA Kit, Cat #635 was performed using several low testosterone samples and two different reagent lot numbers that were assayed twice per day over a period of 3 days. (Reference, CLSI EP 17-A, protocols for Determination of Limits of Detection and Limits of Quantitation).

Limit of the Blank (LoB) pg/mL	Limit of Detection (LoD) pg/mL	Limit of Quantitation (LoQ) pg/mL
1.8	2.1	3.9

C. Precision and Reproducibility:

Intra-assay

The intra-assay precision was determined from the mean of 20 replicates of low, medium and high pools

Sample	N	Mean (pg/mL)	Standard Deviation (pg/mL)	%CV
Low	20	21.0	1.063	5.1
Medium	20	174.7	3.641	2.1
High	20	318.7	13.517	4.2

Inter-assay

The inter-assay precision was determined from the mean average of the duplicates for 12 separated assays with low, medium and high pools

Sample	N	Mean (pg/mL)	Standard Deviation (pg/mL)	%CV
Low	12	19.1	1.232	6.4
Medium	12	155.6	7.106	4.6
High	12	285.5	8.847	3.1

Repeatability

This study was conducted during 5 days of a familiarization period and 20 days of testing. Two assays were performed daily with a minimum of 1 hour between assays. Three (3) different reagents lots and three (3) saliva pools were used for the study (Low, medium and high). The pools were aliquoted and frozen until day of assay.

Precision Study Data Summary

Sample Concentration	N	Mean (pg/mL)	Repeatability		Total Precision	
			SD	%CV	SD	%CV
Low	100	19.4	0.8	3.8	1.1	5.6
Medium	100	155.3	3.7	2.5	7.9	5.3
High	100	275.6	7.4	2.5	11.9	4.0
Control 1	100	19.3	0.9	4.6	1.2	5.8
Control 2	100	201.4	3.8	1.8	8.2	4.0

Inter-lot Variation

The inter-lot precision was determined by duplicate measurements of five (5) saliva samples and two levels of one (1) spiked control in saliva like matrix, using three (3) different reagent lots of Pantex Salivary Direct Testosterone EIA Kits Cat #635.

Saliva Samples ID	Lot # 007 mean (pg/ml)	Lot # 008 mean (pg/ml)	Lot # 009 mean (pg/ml)	Inter-lot mean (pg/ml)	Inter-lot Std. Dev. (pg/ml)	Inter-lot %CV (pg/ml)
1	314.6	324.0	320.1	319.6	4.723	1.5
2	101.8	97.4	99.3	99.5	2.207	2.2
3	69.2	69.4	61.0	66.5	4.793	7.2
4	8.8	9.7	9.9	9.5	0.586	6.2
5	23.8	21.7	21.3	22.3	1.343	6.0
C1	21.1	19.5	20.5	20.4	0.808	4.0
C2	210.2	196.3	212.2	206.2	8.660	4.2

D. **Linearity Study:**

Ten (10) sample concentrations that span the assay measuring range were prepared and assayed per EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures.

S=10 samples (dilutions)
Concentration = (C1*V1 + C10*V10)/(V1+V10)

	C1 pg/ml	V1 ml	C10 pg/ml	V10 ml	Calculated Concentration pg/ml	Observed Concentration pg/ml	Recovery %
1				*	5.5	5.2	94.5
2	5.2	0.889	631.5	0.111	74.7	76.3	102.1
3	5.2	0.778	631.5	0.222	144.2	153.6	106.5
4	5.2	0.667	631.5	0.333	213.8	216.1	101.1
5	5.2	0.556	631.5	0.444	283.3	275.3	97.2
6	5.2	0.444	631.5	0.556	353.4	323.6	91.2
7	5.2	0.333	631.5	0.667	422.9	401.8	95.0
8	5.2	0.222	631.5	0.778	492.5	461.7	93.8
9	5.2	0.111	631.5	0.889	562.0	561.4	99.9
10				*	650.0	631.5	97.2

***** Targets of low and high sample concentrations.

The results demonstrate that the assay is linear from 5.5 – 650.0 pg/mL.
($Y=0.9597x + 3.335$, $R^2 = 0.99685$)

E. Recovery

Seven (7) saliva samples containing different levels of endogenous testosterone were spiked with known quantities of testosterone and assayed.

Sample	Endogenous (pg/ml	Added (pg/ml)	Expected (pg/ml)	Observed (pg/ml)	Recovery (%)
1	10.000	7.813	17.813	19.400	108.9
2	19.000	15.625	34.625	36.300	104.8
3	27.600	31.250	58.850	54.500	92.6
4	28.200	62.500	90.700	95.100	104.9
5	9.800	125.000	134.800	127.900	94.9
6	103.700	250.000	353.700	346.800	98.0
7	38.600	500.000	538.600	497.600	92.4

F. Manual dilution:

A 1:10 sample manual dilution study was performed utilizing six (6) samples to verify the accuracy of the dilution procedure with a dilution factor of 10. The following table indicates the summary of results:

Subject	Observed Endogenous Value (pg/mL)	Testosterone Spiked (pg/mL)	Expected Value (pg/mL)	Observed 1:10 diluted Value (pg/mL)	Applied Factor 10 (pg/mL)	Recovery (%)
AL-209	346.7	0	346.7	33.3	333	96.0
AL-210	274.3	0	274.3	26.5	265	96.6
*AL-225	133.1	500	633.1	67.2	672	106.1
AL-227	229.5	0	229.5	22.7	227	98.9
*AL-228	100	750	850	93.1	931	109.5
*AL-247	125.8	1000	1125.8	121.3	1213	107.7

* Spiked samples.

G. Method Comparison

A comparative study was performed between the Pantex Salivary Direct Testosterone EIA Kit Cat #635 and a FDA cleared predicate device. A total of 106 samples were used for the study (range 6.45–458.35 pg/ml) of which 9 samples were spiked representing 8.5 % (range 252.1 – 424.2 pg/mL) of the total number of samples. The results show the following regression and correlation statistics.

Linear Regression equation	Y = 0.9035X + 5.81
Correlation	R2 = 0.98

XVII. Limitations of the Procedure

1. The Pantex Salivary Direct Testosterone EIA Kit reagents are optimized to measure testosterone in human saliva.
2. Pregnancy or estrogen treatment may lead to elevated salivary testosterone levels.
3. Avoid the use of samples with blood contamination, sodium azide and thimerosal as it may lead to false results.

XVIII. Precautions

1. Only physician, clinical labs, research labs and hospital labs may acquire, possess and use the kit.
2. Compare contents and packing list, if there is breakage or shortage, notify Pantex immediately.
3. Do not pipet reagents by mouth.
4. Do not smoke, eat or drink while performing assay.
5. Wear disposable rubber gloves.
6. Treat all saliva samples as potentially infectious.
7. Do not mix reagent lot numbers or alter in any way the reagents in this kit. If this is done, Pantex will not be responsible for the performance of the assay.
8. Avoid contact with Color Development Reagent (TMB). It contains solvents that can irritate skin and mucus membranes. If contact is made, wash thoroughly with water.
9. Avoid contact with stopping solution. It contains acid. If contact is made, rinse thoroughly with water.

XIV. Selected and Cited Product References

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