

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Urinalysis Reagent Strips

PURCHASE NO.: 37740068B

BATCH NO.: URS0080061

EXPIRATION DATE: 2022-09-04

QUANTITY: 60,000pcs

ANALYSIS		SPECIFICATIONS (Color card)	TEST RESULT
Glucose	Neg. urine	Negative	Complies
	250mg/dL	>100mg/dL <500mg/dL	Complies
Ketone	Neg. urine	Negative	Complies
	Yihua Urine controls	>40mg/dL <160mg/dL	Complies
S.G	1.000	$\geq 1.000 < 1.005$	Complies
	1.025	$> 1.020 < 1.030$	Complies
Blood	Neg. urine	Negative	Complies
	Yihua Urine controls	$\geq ++$ $\leq +++$	Complies
pH	5.0	$\geq 5.0 < 6.0$	Complies
	9.0	$> 8.0 \leq 9.0$	Complies
Protein	Neg. urine	Negative	Complies
	Yihua Urine controls	$> +, \leq +++$	Complies
Nitrite	Neg. urine	Negative	Complies
	Yihua Urine controls	+	Complies
Leukocyte	Neg. urine	Negative	Complies
	Yihua Urine controls	$> +$ $< +++$	Complies

Quality Department: Hedy zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Mission Liquid Urine Control for combo pack

PURCHASE NO.: 37740068A

BATCH NO.: UCL0090001

EXPIRATION DATE: 2022-06-22

QUANTITY: 70kits

ANALYSIS		SPECIFICATIONS	TEST RESULT
Specific gravity	Level 1	1.015~1.030	Complies
	Level 2	1.005~1.020	Complies
pH	Level 1	5.0~7.0	Complies
	Level 2	6.5~9.0	Complies
Glucose	Level 1	Negative	Complies
	Level 2	≥+/- (100mg/dl)	Complies
Protein	Level 1	Negative	Complies
	Level 2	≥1+ (30mg/dl)	Complies
Leukocyte	Level 1	Negative	Complies
	Level 2	≥1+ (70 Leu/μl)	Complies
Nitrite	Level 1	Negative	Complies
	Level 2	Positive	Complies
Urobilinogen	Level 1	0.2(3.5) mg/dL(μmol/L)	Complies
	Level 2	≥+/- (1.0mg/dl)	Complies
Blood	Level 1	Negative	Complies
	Level 2	≥2+	Complies
Ketone	Level 1	Negative	Complies
	Level 2	≥1+ (15mg/dl)	Complies
Bilirubin	Level 1	Negative	Complies
	Level 2	≥1+ (1mg/dl)	Complies
Ascorbic acid	Level 1	Negative	Complies
	Level 2	Negative	Complies
Albumin	Level 1	10~30mg/L	Complies
	Level 2	80~150mg/L	Complies
Creatinine	Level 1	10~100mg/dL	Complies
	Level 2	100~300mg/dL	Complies
Urine Calcium	Level 1	4~10mg/dL	Complies
	Level 2	20~40mg/dL	Complies

Quality Department: Hedy Zhang

Date: Sep. 24, 2020

**ACON BIOTECH (HANGZHOU) CO.,LTD**  
**CERTIFICATE OF ANALYSIS**

**PRODUCT NAME:** Hb Hemoglobin Test Strips

**PURCHASE NO.:** 37740068A

**BATCH NO.:** Hb0070049

**EXPIRATION DATE:** 2022-07-18

**QUANTITY:** 4.000pcs

ANALYSIS			CRITERION	TEST RESULT
SYSTEM ACCURACY (Bias with manufacture control)	Level 0	4.5-5.5g/dL	$\leq \pm 1.0\text{g/dL}$	Complies
	Level 1	6~10g/dL or 10~25.6g/dL	$\leq \pm 0.4\text{g/dL}$ or $\leq \pm 4\%$	Complies
	Level 2	10~25.6g/dL	$\leq \pm 4\%$	Complies
	Level 3	10~25.6g/dL	$\leq \pm 4\%$	Complies
SYSTEM PRECISION	Level 0	4.5-5.5g/dL	$SD \leq 0.8 \text{ g/dL}$	Complies
	Level 1	6~10g/dL or 10~25.6g/dL	$SD \leq 0.4 \text{ g/dL}$ or $CV \leq 3\%$	Complies
	Level 2	10~25.6g/dL	$CV \leq 3\%$	Complies
	Level 3	10~25.6g/dL	$CV \leq 3\%$	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD  
CERTIFICATE OF ANALYSIS

PRODUCT NAME: Urinalysis Reagent Strips

PURCHASE NO.: 37740066C

BATCH NO.: URS0030255

EXPIRATION DATE: 2022-06-27

QUANTITY: 100x100T

ANALYSIS		SPECIFICATIONS (Color card)	TEST RESULT
Glucose	Neg. urine	Negative	Complies
	250mg/dL	>100mg/dL <500mg/dL	Complies
Ketone	Neg. urine	Negative	Complies
	Yihua Urine controls	>40mg/dL <160mg/dL	Complies
Protein	Neg. urine37740053	Negative	Complies
	Yihua Urine controls	>+, ≤+++	Complies

Quality Department: Antong He

Date: July. 02, 2022

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Urinalysis Reagent Strips

PURCHASE NO.: 37740066C

BATCH NO.: URS0030258

EXPIRATION DATE: 2022-03-13

QUANTITY: 1,800x100T

ANALYSIS		SPECIFICATIONS (Color card)	TEST RESULT
Ascorbic acid	Neg. urine	Negative	Complies
	20mg/dl	>10mg/dl <40mg/dl	Complies
Glucose	Neg. urine	Negative	Complies
	250mg/dL	>100mg/dL <500mg/dL	Complies
Bilirubin	Neg. urine	Negative	Complies
	Yihua Urine controls	>++	Complies
Ketone	Neg. urine	Negative	Complies
	Yihua Urine controls	>40mg/dL <160mg/dL	Complies
S.G	1.000	≥1.000 <1.005	Complies
	1.025	>1.020 <1.030	Complies
Blood	Neg. urine	Negative	Complies
	Yihua Urine controls	≥++ ≤+++	Complies
pH	5.0	≥5.0 <6.0	Complies
	9.0	>8.0 ≤9.0	Complies
Protein	Neg. urine	Negative	Complies
	Yihua Urine controls	>+, ≤+++	Complies
Urobilinogen	Neg. urine	Negative	Complies
	4~12mg/dL	>4mg/dl ≤12mg/dl	Complies
Nitrite	Neg. urine	Negative	Complies
	Yihua Urine controls	+	Complies
Leukocyte	Neg. urine	Negative	Complies
	Yihua Urine controls	>+ <+++	Complies

Quality Department: Asst. Mgr. He

Date: July 02, 2020